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IV. Spinal Cord Injury

A. General

Treatment of Central Pain in Spinal Cord Injury: A Pilot Study

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Sponsor: National Institute of Handicapped Research

Purpose — A small but significant proportion of the spinal cord injury (SCI) population develops persistent pain severe enough to interfere with activities of daily living or to become problematic in other ways. While psychological factors are often cited as contributing to the etiology and/or maintenance of chronic SCI-related pain, systematic evaluations of psychologically-based treatment efforts have not been conducted. There is a need to conduct a preliminary investigation of these factors thereby providing a substantive, objective basis for the development of future long-term inquiries into the phenomenon.

This study assessed the effectiveness of a treatment approach for the amelioration of central pain in SCI; determined whether personality measures acquired prior to treatment are helpful/useful in predicting response to treatment.

Progress — The pain treatment protocol developed by Richard Sherman, Ph.D. to ameliorate phantom limb pain in amputations was modified for use with a SCI population. This involved the use of EMG biofeedback, relaxation training, and patient education. Pain assessment procedures used included a pain behavior rating scale, the McGill Inventory, and a subjective pain rating scale. The Minnesota Multiphasic Personality Inventory (MMPI) was administered prior to treatment. Baseline pain data were collected after which the intervention technique developed by Sherman was applied utilizing single case, multiple baseline format. Pain experience/history was re-assessed post-treatment. Results were depicted in multiple baseline, single subject designs. MMPI profiles were compared against treatment outcomes.

Preliminary Results — Five treatment protocols have been completed. A number of other protocols were initiated but not completed due to a variety of reasons (transportation difficulties, patient skepticism, medical complications, etc.) MMPI results did not strongly predict either the severity of pain complaint or treatment outcome. EMG levels (both frontalis and paraspinal) were successfully reduced with biofeedback training by several patients but without apparent impact on subjective pain data. Relaxation training was as effective or more so than biofeedback in reducing pain reports in several patients. Treatment in general seemed more effective for patients with dysesthesia than those reporting severe constant pain.

One outcome of this study preceding the treatment phase was the completion of a normative study of EMG levels in SCI patients and yoked able-bodied adults.

Dr. Sherman is pursuing this normative protocol with a Veterans Administration Hospital (VAH) SCI population. Once completed, comparisons between VAH and non-VAH SCI populations will be possible.

Retrospective Analysis of the National Spinal Cord Injury Care System Database

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Purpose — Systematic and comprehensive management of acute spinal cord injury (SCI) is directed towards reducing morbidity and mortality, increasing life function capacity, and minimizing costs of care associated with this catastrophic condition. Accordingly, it is desirable to establish a mechanism to evaluate performance of the organized management system addressing desired outcomes in such a way that the impact of the system compared to other pre-system or parallel non-system activities is clear. Further, assessment of system performance over time is essential to establish patterns of behavior that then may serve as a rational basis for implementing practice, policy, or programatic change(s), if necessary.

This study is evaluating, retrospectively, the performance of the Model Regional Spinal Cord Injury Care Systems emphasizing quantifiable outcome variables.

Progress — Overall system performance is being evaluated using appropriate statistical procedures. The evaluation methodology includes, but is not restricted to: 1) the relative proportion of all new SCIs brought into and managed by federally-sponsored Model Systems in a given year [national capture]; 2) average time between injury and system admission [mean time into system]; 3) post-admission death rate [mortality]; 4) post-admission medical complication and surgical procedure rate [morbidity]; 5) level of post-discharge independence, place of post-discharge residence, vocational outcome [life function]; 6) post-injury hospitalization experience [length-of-stay and re-admission experience]; and 7) costs characterized on the basis of appropriate epidemiologic variables to facilitate comparisons between early admission and delayed admission patients.

Preliminary Results — Results of the study include information on national capture; demographics, including mean age at injury; sex; race; etiology; life function; level of lesion; extent of injury; functional assessment index; place of residence; occupational status; marital status. Information on admission trends includes: days from injury to system admission; days hospitalized in SCI system; days from injury to system discharge; cost of care; survival rates; primary cause of death; select medical complications; days rehospitalized post-discharge; benefits of early admission to an organized Spinal Cord Injury Care System.

Future Plans — In the coming year we will concentrate our activities on an epidemiologic characterization of associated injuries, operative procedures, and medical complications (with particular emphasis on pressure sores) occurring among patients in the national database.

Diagnosis and Treatment Compatible Spinal Cord Injury Patient Stabilization and Transport Devices

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Progress — The work supported by this PVA grant has resulted in the preparation of tooling and fabrication and delivery for clinical trial of a carbon-fiber/epoxy backboard and improved constant-force traction device for the inter- and intra-hospital transport of acute spinal injury patients. A test frame for a lateral head restraint with one degree of freedom of motion parallel to the traction vector was constructed, and found to be mechanically adequate but needing modification to be useful in a clinical environment. Several specimens of carbon-fiber/epoxy halo were made and laboratory tested; future designs will be similar to Gardner-Wells tongs with integral summing of constant-force traction and minimum X-ray cross-section skull fixation pins.

Contacts have been made with several organizations interested in the problems of movement and diagnosis of spinal injury patients, which may yield benefits not foreseen in the original proposal.

Pain Secondary to Gunshot Wound During the Initial Rehabilitation Process in Spinal Cord Injury Patients

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Purpose — Surgical management of acute gunshot-related spinal cord injury (SCI) is somewhat controversial. There is concern that routine decompression laminectomies (in which the bullet and/or bullet fragments are removed) may aggravate the patient's prognosis rather than improve it. Removal of the bullet tends to be a standard practice irrespective of whether its presence represents a life-threatening situation. It is widely accepted that removal reduces the intensity of associated pain later in life. However, there is virtually nothing in the literature supporting this contention. By contrast, other clinicians believe laminectomy may contribute to general instability of the vertebral column in addition to being partially responsible for some reported pain. Finally, there is a clinical impression that pain occurring secondary to gunshot wound may differ in character from that occurring secondary to SCI resulting from other causes.

This study will help clinicians understand intractable pain following SCI. It also will verify or refute the efficacy and desirability of decompression laminectomy and bullet removal after SCI. Specifically, it seeks to: 1) determine whether the incidence of pain reported in GSW/SCI patients is significantly different than the incidence in patients whose SCIs result from other etiologies; 2) characterize the incidence of pain reported by GSW/SCI patients epidemiologically and demographically; 3) determine the relationship between incidence of pain in GSW/SCI patients and surgical removal of the bullet; and 4) document the incidence of pain in GSW/SCI patients with or without decompression laminectomy.

Progress — This is a two-phase, prospective study. In Phase 1, pain data are being collected on all SCI admissions (except those excluded because of overlying psychosis or senility) on a weekly basis from time of admission to first definitive

discharge. Pain behavior changes are being accessed over time. Data are being evaluated with regard to epidemiologic and demographic characteristics of the population. GSW/SCI patient data are being studied to determine absence or presence/location of the bullet or bullet fragment(s). If surgically removed before this phase, the pre-surgical location is being documented. Pain history is being documented and analyzed statistically. Eventually, all findings will be reviewed with our Department of Neurosurgery and a Phase 2, controlled study with random assignments of patients to surgical/non-surgical management groups will be undertaken. Patient outcome will be evaluated.

Preliminary Results — Presently, we are evaluating all admissions to determine if specific patients can be relied upon to provide accurate data. We are collecting weekly pain data (pain behavior, subjective (0-10) ratings, and the McGill Pain Inventory) on GSW/SCI patients during their initial hospitalization, and at six and 12 months post-injury. As of December, 1984, 18 GSW/SCI patients have been entered into the five GSW study groups: 1) bullet in canal (n = 4); 2) bullet present elsewhere (n = 4); 3) bullet removed from canal (n = 6); 4) bullet removed from elsewhere (n = 3); and 5) bullet exited body (n = 1). We also are collecting identical data on a control group of 50 non-GSW/SCI patients matched by neurologic level and extent of lesion, and in most cases by sex.

Future Plans — Data collection will proceed through May, 1987.

Aging and Spinal Cord Injury: Research Needs Study

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Purpose — Beginning in November, 1984, the project's purpose was to report the status of research in aging and spinal cord injury. The project strategy was for a three-part approach. First, conduct a literature search into the medical, psychosocial, economic, environmental, and support services issues associated with aging in the spinal cord injured. The search would include books, scientific journals, and conference papers and/or reports. The priorities for the search were specific to aging and SCI, aging and other chronic disabilities, and finally a general search on gerontology. The second approach called for Dr. Trieschmann to conduct three small conferences of aging SCI individuals and their spouses. These conferences would provide an opportunity for individuals to share their concerns and priorities during the aging experience. The final approach was to interview select professionals in SCI who might be able to verify and/or dispute information/trends identified during the first two approaches.

Progress — After six months, the project has become involved actively in all three approaches. As assumed in the design of the literature search, there was found to be a small amount of specific relevant research literature. It was somewhat unexpected that the amount of literature on aging and other chronic disability also was very limited. On the other hand, the general search of gerontology literature necessitated further limitations to prevent it from over-

whelming project time. Regarding the small consumer conferences, Dr. Trieschmann found that due to very real human considerations the aging SCI person and his/her spouse was not disposed positively to sharing personal concerns and priorities in a conference setting. Their eagerness was much greater in the privacy of an interview session. Dr. Trieschmann has contacted select individuals and invited them to interview regarding their experiences with the aging process. These small interviews have proven to be insightful in matters ranging from spouse survival and the reliability of the veteran's benefits for his family upon his death to confidence in the present medical profession and its apparent lack of experience in dealings with the problems of aging SCI persons. Many voiced concern that current medical interventions for the kinds of problems facing the aging population were untested with regards to the aging SCI person, making it difficult to remain confident that current accepted practices would be safe for them.

The interviews with selected professionals have been conducted by Dr. Trieschmann through contacts at conferences and/or conventions, or through initiated personal contacts around the country. These interviews have confirmed some concerns among the SCI population, and providing further introductions to individuals knowledgeable in these issues. The project is scheduled for completion in November, 1985.

Economic Consequences of Severe Disability

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Purpose — Researchers at the Bureau of Economic Research at Rutgers University are conducting a study funded by PVA's Spinal Cord Research Foundation to assess the economic consequences of spinal cord injury. New surveys of the spinal cord injured population are necessarily expensive and time consuming, so we are attempting to use existing data sources such as the 1978 Social Security Survey of Disabled and Nondisabled Adults and the Health Interview Survey to shed some light on the economic consequences of spinal cord injuries. These general surveys contain a wealth of economic information about disabled persons. We plan to compare the economic status, medical expenses, transfer payments, functional limitations, and a host of other relevant variables of spinal cord injured persons with other disabled persons or with demographically comparable nondisabled persons.

Progress — Three issues that impact on this study of the economic consequences of SCI are being intensively studied: 1) methodological problems in using secondary data sources to identify persons with specific disabling conditions; 2) potential benefits and costs of vocational rehabilitation; and 3) differences in health care use and expenses among persons with different disabling conditions.

All three aspects come together in the models designed to predict earnings and labor force participation of the severely disabled population. It is in the labor market where one observes the greatest economic consequences of spinal cord injuries and other severe disabilities. Detailed information collected in the surveys

on health status, insurance coverage, and receipt of such transfers as veterans' compensation, Social Security Disability Insurance, and Supplemental Security Income can be incorporated into the standard models of labor market behavior.

The results could be useful in pinpointing and measuring disincentive effects of benefits programs as well as evaluating the consequences of changes in program eligibility rules.

Phantom Sensations Experienced by Complete Spinal Cord Injured Veterans

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Sponsor: VA Rehabilitation Research and Development Service and U.S. Army Clinical Investigation

Purpose — Our clinical experience and initial research have led us to believe that pain which appears to come from areas below the level of normal sensation among people with spinal cord injuries is far more common and debilitating than has been supposed. This type of pain is frequently referred to in the literature as phantom body pain. It is an uncomfortable sensation that feels as though it is coming from an area of the body no longer having sensory nerve connections with the brain. The most common example is the pain experienced by amputees which they can describe in great detail as coming from a particular portion of the amputated limb. Spinal cord injured people who clearly have no normal sensations from a particular area below the level of spinal cord interruption frequently report pain from that area.

Progress — Thirty-five patients with clinical diagnoses of complete transverse spinal cord tissue destruction were interviewed about any sensations they felt below the level at which normal feelings were evident. All reported experiencing various feelings most of the time and thirty-three reported that some of those feelings were usually quite painful. Videothermographs showing differences in skin temperature of 0.1 degrees celsius were taken to evaluate blood flow patterns to a depth of 1.5 centimeters. Changes in blood flow patterns were found to correlate highly with the level at which sensations changed from normal to abnormal and to correlate virtually exactly with the locations of pain reported from supposedly desensate areas.

We propose to survey enough spinal cord interrupted veterans (5,000) to determine the actual characteristics, prevalence, and severity of pain below the level of normal sensations. The survey also will cover treatment effectiveness. This will establish if there is a major unrecognized problem not being adequately dealt with and, if so, give us a basis for understanding it. Mail response surveys will be sent to 5,000 spinal cord injured veterans identified by the Veterans Administration.

We also propose to carry out physiological evaluations of muscle tension and blood flow among at least 100 spinal cord interrupted veterans to look for correlations between phantom body pain and changes in these parameters. Multiple recordings will be done on each patient so changes with pain intensity and time can be evaluated and controlled. If we do confirm and extend these correlations, in further research we can apply modified versions of our reasonably successful phantom limb pain treatments to phantom body pain. We hope this will result in the development of good, lasting treatments for a currently difficult problem.

Spinal Cord Studies

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Use of Hyperbaric Oxygen in Patients With Spinal Cord Injuries

Forty-six patients have now been treated with hyperbaric oxygen, most receiving two treatments, each of 90 minutes duration with two hours between each treatment. We continue to use 2.5 ATA. Patients who have incomplete spinal cord lesions still appear to recover more quickly than would otherwise have been expected. Final motor and sensory recovery in these patients is still being assessed and compared with those patients who received treatment without the use of hyperbaric oxygen.

Study of Cortico/Sensory Evoked Potentials (SEP)

This project initially involved studies in 250 patients. Patients continue to be investigated on admission in order to assess the degree of spinal cord injury during the period of "spinal shock." Portable equipment is now available to facilitate studies on spinal cord function in patients within hours of injury.

Study on the Life Expectancy of Paraplegic and Quadriplegic Casualties

This study is continuing to provide information on reduction of life expectancy in paraplegic and quadriplegic casualties admitted to the specialized Spinal Units, and receiving adequate follow-up care on discharge. Results of this project are now in the final stages of analysis and are being prepared for publication.

Development of a Portable Respirator

Further developments have resulted in the supply of a suitable portable respirator for use by a high level quadriplegic patient returning to a country area to live. The "Life Pack" portable respirator widely used in North America is now being assessed for patients returning to remote areas in this country.

Supra-Pubic Drainage of The Neurogenic Bladder

The "Cystocath" has now been used for several years as a means of avoiding overdistension and infection in the neurogenic bladder. The initial analysis of 60 patients who had immediate drainage of the paralysed bladder with supra-pubic catheter drainage confirms that 77 percent of these patients have remained free of significant urinary tract infection and avoided over-distension of the bladder prior to bladder training.

Development of Low Cost Appliances

Sixty-five lightweight plastic wheelchairs have been built with improvements to meet the various needs of patients, both here in Australia and in the South Pacific areas. This research project is continuing with the development of other specialized equipment for high level quadriplegics. Environmental controls are being studied and adapted for individual patient use. The emphasis is put on using readily available materials.

Education And Prevention Program

Four researchers are involved in presenting an Education and Awareness Program in order to reduce the incidence of spinal cord injury in the community.

Over 80,000 school children have been contacted through presentations by the four members of the Resource Team. An analysis of the success of this Education Program will continue.

The Computer Training Program

A computer has been installed in the Occupational Therapy Department and patients are being trained in the use of the computer in order to widen the prospects for employment on their return to the community.

The Use of EMG Biofeedback and Functional Electrical Stimulation in Spinal Cord Injury

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Purpose — The purpose of this project is to determine the relative effectiveness of Electromyographic (EMG) Biofeedback, Functional Electrical Stimulation (FES), Occupational (OT) and Physical Therapy (PT), and specific combinations of these modalities on the restoration of function in persons with spinal cord injuries.

Progress — Eighty persons with incomplete spinal cord injuries at level C3 through C7 with resulting quadriparesis will be matched according to level of injury, muscle strength, EMG recruitment and activities of daily living, and then be randomly assigned to one of four groups: 1) EMG Biofeedback-FES; 2) EMG Biofeedback-OT, PT; 3) FES-OT, PT; and 4) OT, PT-OT, PT. Eight weeks of each treatment modality will be provided two to three times per week in sequence. Measurements of muscle strength, EMG recruitment, active and passive range of motion, and functional performance in activities of daily living will be taken prior to the start of the experiment after each treatment segment and at a six-month follow-up.

EMG recruitment will be measured by a specially designed multi-processor computer system. This unit also will provide the EMG Biofeedback on several muscle sites simultaneously according to pre-established operant conditioning procedures. Passive and active range of motion will be measured with goniometers and standard testing procedures. Muscle strength will be measured on a five-point scale using standard OT-PT procedures. Functional activities of daily living will be assessed by instruments specifically designed for this study. The OT and PT treatment will be provided by therapists with expertise in spinal cord injury according to standard treatment protocols for increasing function. FES will be provided by a computerized system according to the pre-established protocols.

Preliminary Results — The measurement instruments to be used in this study have been developed and tested, the treatment protocols have been established, and personnel, equipment, and supplies are being acquired. In addition, the possible subject population have been identified and initial screening of subjects is currently taking place.

P. L. 480 Paraplegia Project, Madras

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Sponsor: National Institute of
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Purpose — The main aim of the Paraplegia Project, Madras, is to develop simple methods of care of SCI patients in a general hospital set-up without reliance on expensive equipment. Such methods, if found to be effective and useful, have the merit of immediate transfer of appropriate technology to other parts of India and other developing nations with socio-economic conditions similar to India.

The specific objectives are to:

1) Establish within the catchment area of Madras City and adjoining districts within a radius of 200 miles, a multidisciplinary system of care providing comprehensive services to meet the wide range of needs of persons disabled by spinal cord injury. This will take place from the point of injury, requiring emergency treatment and transportation, through acute care, and early rehabilitation (including vocational and educational preparation, job placement, and long-term follow-up).

2) Demonstrate and evaluate the effectiveness of the system with regard to benefits to the spinal cord injured person and determine the cost of care for each. Specifically, it is anticipated that the system approach when compared to the non-system will result in: decreased incidence of spinal cord injury; decreased mortality; decreased morbidity; that is, less extensive spinal cord damage and fewer complications; increased function in terms of independence in activities of daily living, mobility, educational and vocational achievement; and, decreased duration and cost of acute and rehabilitation care.

3) Demonstrate and evaluate simple methods of care consistent with available resources and without emphasis on costly bed systems and equipment.

4) Facilitate education of medical and allied personnel in the management of spinal cord injury and of the public for the prevention of spinal cord injury.

5) Establish within the system a rehabilitation research environment of knowledge leading to reduction or treatment of complications arising from spinal cord injury.

6) Develop and maintain effective administration and resources to a high level of system performance.

Progress — Four hundred and ninety-nine SCI patients were treated from January, 1979 through December, 1983. Nearly 90 percent of the patients were males. Falls from heights or into wells were the commonest modes of injury (66 percent). The patients admitted within 72 hours and those admitted after that period were called System and Non-System cases, respectively. The majority of patients were treated by conservative regimen. The Madras method of acute care of flexion injuries of the spine is considered the most significant contribution of the study. The neurological status of SCI patients in this study showed statistically significant improvement when compared to several centers in other countries, with the exception of Tokushima series from Japan (where the common mode of injuries was also falls).

The incidence of pressure sores declined drastically with the two-hourly turning schedule of the Madras method. Nineteen percent of System cases and 45 percent of Non-System cases had pressure sores.

Psychosocial and vocational rehabilitation was given for all surviving patients. One hundred and fifty-two mobility aids and appliances were given free of cost to patients needing them. One hundred and forty of 393 System patients were vocationally rehabilitated. Psychiatric and psychological studies were done on 31 patients. Appropriate counselling helped these patients.

The PL 480 Paraplegia Project in Madras has proved the feasibility of acute and intermediate care of SCI patients by simple methods in a general hospital set-up of a large teaching hospital. The Madras model is worthy of replication in developing countries.

Acute Spinal Injury Patient Transportation and Support Devices

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Purpose — The goals of this project are to design, fabricate and test in laboratory and clinical settings equipment for supporting and moving acute cervical spine injury patients compatible with helicopter transportation and in-hospital computerized tomography, nuclear magnetic resonance scanning and similar diagnostic or therapeutic modalities.

Progress — Under a grant from the Paralyzed Veterans of America Spinal Cord Research Foundation, a series of six carbon fiber/epoxy foam-core backboards with multiple constant-force traction devices are to be fabricated and distributed to Santa Clara Valley Medical Center (and to other spinal treatment centers selected by Dr. Wilmot of SCVMC). Other aspects of the funded project include construction of several working models of lateral head restraints, design and fabrication of X-ray compatible carbon fiber/epoxy halos or tongs for skull fixation, and conceptual modeling of equipment including the backboard/traction device as an integral part of long-term patient maintenance. Advanced studies of methods of improving communication of patient status as the patient is transferred between treatment centers, and of provision of therapies such as hyperbaric oxygen and thyrotropin-releasing hormone (TRF) during transport are under consideration.

A technique for low-cost fabrication of carbon fiber composites has been devised. A traction device meeting the force and dimensional constraints has been developed combining the best features of two previous designs. Laboratory testing of these devices will include 4-point bending tests to determine ultimate strength of samples of the backboard composite, load-deflection test of complete backboards, including one test to failure, and force output tests of traction springs at constant extension rate. Clinical use of the devices will be monitored and data on staff acceptance and patient welfare will be analyzed and compared to historical records. Negotiations have been entered into with a potential manufacturer, using an automated reaction-injection-molding method rather than hand lay-up of the backboards. A tentative agreement has been reached with the helicopter development group at NASA-Ames Research Center to measure vibration and acceleration on an instrumented dummy on various forms of backboards during helicopter transport.

Preliminary Results — Two of the backboards and one traction device of the new design have been completed and are in use by SCVMC and Stanford University's "Life Flight" helicopter team. A third board and five traction devices are under construction. Three filament-wound halos have been made (one tested to failure) and molds are being made for carbon fiber tongs incorporating a novel fixation pin design. Hospital staff acceptance of a mock-up head restraint was less than favorable, and this design is being revised. Bending tests of backboard composite samples showed adequate flexure strength. Tests of traction devices showed hysteresis in the force output between extension and retraction; changes to correct this have been incorporated. Papers describing these results and the two-year experience with an earlier prototype at SCVMC have been submitted for presentation at 1985 RESNA and ACEMB Conferences.

Outcome Studies Pertinent to the National Model Spinal Cord Injury System

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Purpose — This project encompasses three studies, two retrospective and one prospective, aimed at providing additional evidence about the effectiveness of the National Model Spinal Cord Injury System Project administered previously by RSA and currently by NIHR.

The two retrospective studies capitalize upon existence of the common database established by the national systems. One study is an attempt to demonstrate that the highly advanced system of care practiced at the Royal Perth Hospital in Australia results in better patient outcomes than obtained in the less advanced care systems in the U.S.A. The second study is concerned with documenting post-rehabilitation outcomes for quadriplegic patients who, at discharge from inpatient rehabilitation, require ventilatory assistance.

The prospective study will compare the outcomes of two groups of patients. One consists of patients whose acute and rehabilitation care was provided by the Texas/South Central Regional Spinal Cord Injury (T/SCRSCI) System. It is comprised of four acute care hospitals in the Houston-Galveston area and of The Institute for Rehabilitation and Research (TIRR) as the rehabilitation setting. The second group will consist of patients who were discharged from the same four acute care hospitals but who did not receive rehabilitation services at TIRR. Data for TIRR patients are being obtained in a companion project entitled, "Assessment, Development, and Clinical Application of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge." Data for non-TIRR patients will be obtained during home interviews using an adapted form of the interview used in the companion project.

Progress — During the project's first year, the U.S.-Australian systems study directed by Dr. William Donovan was completed, and an article is in press in Paraplegia. In that study, one data set reflected experience with 65 consecutively admitted patients whose care during 1979 and 1980 occurred in the spinal cord unit at the Royal Perth Rehabilitation Hospital in Perth, Western Australia. A second data set pertained to 1606 U.S. patients who had been cared for in one of the regional systems during the same two years.

The results indicate that decubitus ulcers, atelectasis, pneumonia, pulmonary emboli, ulcers of the gastrointestinal tract, and heterotopic ossification all occurred more frequently in the U.S. group. The difference was particularly marked for decubitus ulcers and urinary tract infections. These outcomes demonstrate that the sooner spinal cord injured patients are referred to a center capable of meeting all their needs, the less likely it is that they will develop complications that slow rehabilitation progress.

Analyses for the study concerned with post-rehabilitation outcomes for ventilatory dependent quadriplegics are nearing completion, and the prospective study comparing outcomes for system and non-system patients is continuing.

Longitudinal Assessment of Physical Therapy Factors in the Rehabilitation Process that Affect the Quality of Life of Persons with Spinal Cord Injury

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Progress — The primary objectives of this study are to: 1) determine the importance of the patient's compliance in performing weight-shifts in a wheelchair to prevent breakdown of skin in weight-bearing areas of the body; 2) improve the criteria and procedures for selecting which spinal cord injured patients should be braced and trained to become functional ambulators; and 3) determine the incidence, characteristics, and outcome of pain complaints in patients with severe spinal cord injury.

Progress — Reductions in the original level of funding necessitated reduction in the scope of the project being undertaken. Considering the resources and expertise available, we elected to defer action on objective 1 and concentrate on objectives 2 and 3. As we complete work on objectives 2 and 3, we will redirect staff effort to pursue objective 1. Patients being studied are individuals who received severe injuries to their spinal cord resulting in paraplegia or quadriplegia.

A total of 70 patients between the ages of 20 and 58 years with paraplegia have been studied in pursuing Objective 2. A list of patient attributes and equipment and services associated with the gait training program was compiled for each patient. Follow-up evaluations six months to several years after bracing are being made to assess brace utilization. We expect the results to improve the criteria for selection of those who will remain users of braces.

A total of 135 patients between the ages of 11 and 80 years (74 with quadriplegia and 61 with paraplegia) are being studied in pursuing objective 3. Information on pain status, method of treatment, and reported success of treatment is gathered on a weekly basis until time of discharge. We expect the results to illustrate trends in the etiology and resolution of pain complaints.

Preliminary Results — Thus far we have: 1) analyzed the results of brace utilization by 70 patients who received bilateral knee-ankle-foot orthotic devices and drafted a report of the findings; 2) begun pilot studies with an orthotist to devise a simplified, modular, lightweight orthotic device for early bracing and gait training; 3) gathered and categorized data concerning the pain complaints made by 135 patients with spinal cord injury during their initial hospitalization for

comprehensive rehabilitation; 4) examined correlations between population variables, etiology of injury, level and neurological completeness of injury, and location and suspected etiology of pain complaint; 5) documented the status of each pain complaint at the time of discharge; 6) identified therapeutic procedures that patients reported as most effective in alleviating individual pain states; and 7) initiated a prospective study designed to test the relative effectiveness of specific therapeutic interventions in alleviating particular types of pain.

We plan to continue analyzing these data to look for relationships that will shed additional light on the mechanisms responsible for the state of discomfort and the mechanisms responsible for alleviation of discomfort.

Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge

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Purpose — There are three major project objectives: 1) assess current strategies employed after discharge to achieve psychosocial adjustment and productive lives for spinal cord injured persons; 2) develop and test new strategies or refine current strategies to enhance outcomes postdischarge; and, 3) facilitate the integration of new and tested strategies into the service delivery system at The Institute for Rehabilitation and Research (TIRR) and disseminate the strategies to other appropriate sites. Methods include interviewing rehabilitation professionals and spinal cord injured clients to assess needs and resources, collaborating with service providers to develop and test improved strategies to address unmet needs, and assisting integration of the improved strategies into the service delivery system. Approximately 150 spinal cord injured persons over 14 years of age who were admitted to TIRR for comprehensive rehabilitation from 1979 to the present will be interviewed. Rehabilitation professionals from a variety of disciplines will be interviewed and/or serve as an advisory committee. The benefits expected from this project include meeting needs early to avoid compounding problems, utilizing resources efficiently by tailoring programs to meet the actual needs of clients, and improving rehabilitation outcomes by providing appropriate services.

Progress — A protocol was developed for interviewing rehabilitation professionals. Eight professionals from six rehabilitation disciplines were asked to describe the needs of SCI clients following discharge, the resources available to meet those needs, and the systems for linking the clients with the appropriate resources. Eight broad categories emerged: Health, Activities of Daily Living, Living Arrangements, Vocational, Psychosocial, Transportation, Financial, and Societal Issues and Policies. The list of needs described by the professionals was used to develop an interview protocol for use with clients to determine needs, utilization of formal and informal resources, how they found out about resources, satisfaction with resources, and special difficulties encountered in meeting their needs.

From a pool of approximately 600 eligible clients, 115 interviews have been completed. Data collection will continue throughout 1985. Preliminary analyses of the first 97 interviews indicated major differences in selected variables when subjects were grouped by race, sex, extent of injury, and time since injury. For

example, 31 per cent of the whites were employed, whereas 22 per cent of blacks and 8 per cent of hispanics were employed. Males had an average monthly income of $1156 and the average for females was $611. We are working collaboratively with the National Spinal Cord Database and the RTC project on Outcome Studies Pertinent to the National Model Spinal Cord Injury System.

Longitudinal Assessment of the Utilization of Upper Extremity Assistive Devices Prescribed for the Spinal Cord Injured Quadriplegic

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Sponsor: National Institute of Handicapped Research

Purpose — Upper extremity assistive devices are frequently prescribed during the rehabilitation of SCI quadriplegics. However, though these devices are used daily during hospitalization, they may be discarded once the individual leaves the hospital environment. The primary objectives of this study are to: 1) identify functional categories of assistive devices prescribed for quadriplegics; 2) determine utilization of and satisfaction with those devices one year and two years following rehabilitation; and 3) determine factors responsible for discarding devices.

This is a longitudinal prospective investigation in two parts. Phase I of this study is a review of 102 charts of quadriplegics to determine functional categories and frequency of prescription of upper extremity assistive devices. Phase II employs an oral questionnaire of 75 patients to ascertain utilization of and satisfaction with devices prescribed during a first rehabilitation experience. This questionnaire is administered one and two years following discharge.

Satisfaction is determined using a Likert scale. It addresses the device characteristics of fit, cosmesis, mechanical, and functional performance. Factors that result in discarding a device include improved physical function, mechanical failure, alternative solutions, modification of living arrangements non-compliance, device outgrown or unattractive.

Progress — One hundred and two charts of quadriplegic patients were reviewed to establish the functional categories and frequency of prescription of upper extremity assistive devices. Feeding devices were prescribed to 49 percent of patients, splints and slings 87 percent, dressing 30 percent, hygiene/grooming 22 percent, and communication 20 percent. An oral questionnaire developed to determine device utilization and level of satisfaction was administered to 77 former patients one year following their first rehabilitation experience. Two hundred and sixty-two devices had been prescribed; 67 feeding, 116 splints and slings, 18 dressing, 19 hygiene and grooming, 30 communication, and 12 miscellaneous. At the end of one year, 151 devices (58 percent) were still in use (36 feeding, 75 splints/slings, 7 dressings, 8 hygiene/grooming, 17 communication, and 8 miscellaneous). On a scale of 1-5 (5 being the most satisfactory), those devices still in use were rated an average of 4.24. The most frequently cited reasons for discarding devices were improved physical function and alternative solutions found. Discarded devices represented a cost of $5400 or 35 percent of the total expenditure for all devices.

Twenty-four of the original population were queried two years post-rehabilitation. Sixty-seven percent of the devices prescribed during their first

rehabilitation experience were still in use two years later with an overall level of satisfaction of 4.14 with retained devices. The remaining 53 subjects will be queried and the data recorded.

Preliminary Results — The results of this study already have influenced some of the prescription practices within the occupational therapy department. Therapists consider less expensive short-term devices rather than ordering the most expensive models of the same item. Furthermore, the OT staff is relying more on department-owned equipment from which patients may be weaned prior to discharge. Data on specific devices are being scrutinized to establish practical guidelines for their continued prescription.

Documenting and Utilizing Programs Which Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury

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Purpose — The purpose of this project is to collect and maintain information about independent living and community adjustment programs that serve spinal cord injured people, to provide an effective means of communicating new ideas and experiences between individuals operating these programs, and to provide access to a dependable source of technical assistance related to these programs.

Progress — Non-experimental survey methodology is being used. The data are summarized in frequencies according to specified categories of interest, and some correlational studies are being done to determine trends in independent living program development. Data from project surveys are used to assess the types of services being provided for persons with spinal cord injury, and the source and amount of funds being utilized.

In order to facilitate use of the information which is developed, the project maintains a telephone communication network with all the extant independent living programs and approximately 150 additional individuals. Knowledge transfer strategies depend on the specific topic or set of information, but they usually involve extensive reviews of existing literature, interviews with independent living program administrators, staff members, and consumers, and supplementary reviews by additional experts both in and out of the independent living field.

Preliminary Results — The findings of this work are being disseminated in several forms. A directory listing all identified independent living programs is in its second edition. A registry profiling 164 independent programs in detail is available to spinal cord injury treatment programs, persons with spinal cord injuries, and others interested in independent living. An analysis of the data listed in the registry is in press as well as a monograph in the ILRU Occasional Paper series. The ILRU project is continuing its training, networking, and information dissemination activities in the area of independent living and maintains an ongoing effort to update its databases.

Vocational Evaluation for Quadriplegics with a High School Education or Less

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Purpose — The project objective is to develop a vocational evaluation process that will expand the vocational options for spinal cord injured persons who are quadriplegic, who have a high school education or less, and who have either a limited work record or a job history incompatible with current functional limitations.

Methodology involves: 1) identifying and documenting jobs that can be performed by the described population group; 2) conducting a comprehensive review of existing vocational assessment tools and determining relevance of tools to assess the potential of quadriplegics; 3) selecting and organizing a meaningful process; 4) incorporating the model vocational process into the Vocational Department's service delivery program; and 5) evaluating the effectiveness of the model evaluation process.

The expected outcome of this project is the establishment of a more effective and realistic vocational evaluation process that can be used to assess the job potential of quadriplegics. The project also may have implications for other disability groups with severe physical impairments.

Progress — This project is nearing completion of the developmental phase. Of 12,278 jobs that have been reviewed, 497 have been judged by the project staff to be options for quadriplegics with a high school education or less.

A total of 334 vocational assessment tools have been reviewed. Of this total, 55 commercial work samples, 18 non-commercial work samples, and 15 psychometric tests were determined by the project staff to be within physical capabilities to be performed by quadriplegics. Activities planned for the forthcoming year include: 1) identifying the occupational outlook of the jobs identified as suitable for quadriplegics; 2) selection of assessment tools applicable to measuring potential for identified job options; and 3) organization of the vocational evaluation process.

Development of Reconditioning Exercise Program for Patients with Paraplegia

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Purpose — The overall purpose of this project is to develop a testing methodology and to evaluate an exercise training program for the physical reconditioning of the patient with paraplegia. The expected outcome is the formulation of guidelines for the prescription of exercise and the documentation of the effects of physical conditioning programs for the patient with paraplegia. Male paraplegics between 18 and 50 years of age, free from disorders which contraindicate relatively high levels of exercise, and who have reached a suitable status in their rehabilitation process, will be selected for participation in the project. A minimum of five patients is to be studied in each of five categories of training modalities. Each participant will be initially administered an exercise stress test consisting of interviews, blood sample for biochemical analyses, resting ECG, physical exam, and a graded arm ergometry test using an interrupted steady-state

protocol. Expired gas will be collected during the last minute of each exercise phase. The training program modalities will consist of prescribed unsupervised exercise at home or exercises in a gamefield especially designed for wheelchair patients. Other patients will perform prescribed exercise under supervision in the laboratory or gamefield. Initially, the exercise period is for five to ten minutes increasing to 20-25 minutes with training. Training will be three days per week for eight to 12 weeks. After training, the patient will be subjected to a post-training study in which the testing of the first study will be repeated.

Progress — Methodological accomplishments this year have been the inclusion of blood lactate determinations to the biochemical studies being conducted. Monitoring of heart rate during physical exercise can now be accomplished by portable battery-powered telemetry systems.

The assessment of the cardiovascular tolerance to physical work with arm exercise has been extended to 22 untrained paraplegic males, some more than one time, and to eight healthy males tested in the same manner for obtaining comparative data. One well trained paraplegic male was tested following a self-imposed training program. Other paraplegic males have been placed on prescribed physical exercise training programs under close laboratory supervision and unsupervised training at home. One paraplegic patient has been tested in the gamefield following training. The healthy subjects were tested in the laboratory using both arm and leg exercise. Four participated in testing in the gamefield.

B. Medical Treatment

[See also pgs. 41, 42, 150, 154, 203, 204, 207, 230]

An Ultrasonic Bladder Sensor for Persons with Incontinence

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Purpose — The purpose of this project is to develop and evaluate an unobtrusive, portable device that will continuously monitor bladder volume using ultrasound. Such a device will assist persons with mental retardation who have not learned independent toileting skills to learn the association between the internal state of bladder distention and the act of engaging in a toileting routine; it also will allow persons with inadequate sensation to independently monitor their internal state.

Progress — In the first year of funding, project goals include: 1) the establishment of a comprehensive database of research and clinical reports on incontinence, of centers investigating incontinence, and of manufacturers of assistive devices for incontinence; 2) the determination of anatomical/physiological parameters for proper positioning of the bladder sensor; 3) the development of a breadboard/rack-mounted prototype of the sensor; and 4) the design of, and arrangement for, the extended behavioral research to evaluate the prototype in client service settings. At the time of writing, over 40 patients at the Medical College of Virginia were tested to determine the parameters of a bladder's internal

positioning. An extensive computerized database on incontinence articles, vendors, and research centers was established and offers free computer access to any interested party. Experimental design of the Beta field tests was developed.

Future Plans — In the remaining two years of the project, the extended Beta tests will be conducted in vocational programs of the ARC-Peninsula and in classrooms of the Dallas Independent School District. Objectives of the behavioral research are to: 1) collect information on the durability, reliability, and flexibility of the initial bladder sensor design; 2) quantify and validate the utility of the sensors in providing increased independence in toileting; 3) provide a solid base for the eventual marketing efforts of the bladder sensor; and 4) develop information on the appropriate use of the sensor and guidelines on its application for eventual users and their teachers, parents, and aides. Refinements will be made based on the results of these tests and the modified prototype will be miniaturized.

Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction

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Sponsor: National Institute of Handicapped Research

Purpose — Appropriate clinical management of patients with neurogenic bladders resulting from spinal cord dysfunction requires 1) knowledge of the natural history or clinical course of urinary tract complications in this group and 2) data from which to determine whether urinary complications in this group are predictable from early post-injury urinary tract status and methods of early bladder drainage management.

The objectives of this study include: 1) determining the effect of method of bladder drainage management on orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, calculi, and effective renal plasma flow (ERPF); 2) determining the effect of various urinary tract infecting organisms on orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, calculi, and ERPF; 3) determining the effect of vesico-ureteral reflux on upper tract changes including ureterectasis, pyelocaliectasis, calculi, and ERPF; 4) determining the effect of pyelocaliectasis on cortical thickness and development of renal calculi; and 5) determining the effect of bladder calculi on bladder configuration changes, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, cortical thickness, and renal calculi and the effect of renal calculi on pyelocaliectasis and cortical thickness.

Progress — Rigorous statistical analysis is being performed on a massive urologic database derived from a large series of SCI patients having a spectrum of neurologic levels and extents of injuries, and whose neurogenic bladders are/were managed in a variety of ways.

Preliminary Results — Complete studies have been performed and data recorded on 327 patients from a retrospective study group and 485 patients from a prospective group, yielding a total of 812 completed studies to date. Of 812 patients with comprehensive data, 288 (35 percent) had valid effective renal

plasma flow data one year post-injury. Neurologically incomplete paraplegics had the highest total ERPF one year post-injury (578 mls), while neurologically incomplete quadriplegics had the lowest (506 mls). In general, there was a slightly decreasing trend in total ERPF over time among all four neuro-categories. Mean ERPF of the worst kidney was highest for neurologically incomplete paraplegics one year post-injury (271 mls) and lowest for neurologically complete quadriplegics (227 mls). Once again, a slightly decreasing trend over time was observed among all four neuro-categories.

Based on the statistical analysis, the occurrence of renal stones is the most important factor leading to a diminished renal function (ERPF). Of 812 patients with adequate data, 512 (63 percent) had valid data reflecting the occurrence of renal stones during the first post-injury year. The risk of renal stones has been consistently highest among neurologically complete quadriplegics, ranging from four percent in year one to 22 percent in year eight. Interestingly, no renal stones were diagnosed among neurologically incomplete paraplegics more than three years post-injury.

Objective 4 and portions of Objective 5 have been completed. Analysis of the remaining objectives is currently underway.

Future Plans — Data collection continues. We plan to focus our attention on methods of bladder management and their association with urologic complications including orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, vesico-ureteral reflux, ureterectasis, pyelocaliectasis, calculi, and ERPF.

Effectiveness of Prophylactic Anti-Microbial Therapy in Patients with Neurogenic Bladder

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Purpose — The ultimate goals of an intermittent catheterization program (ICP) for patients with neurogenic bladders include removal of the indwelling catheter and maintenance of sterile urine. Recurrent urinary tract infections (UTIs) are among the most frequent causes of rehospitalization in the spinal cord injury (SCI) population. Any therapeutic modality capable of successfully assisting in maintenance of sterile urine will be an invaluable adjunct to the prevention of renal deterioration. There is a clinical need to know the relative efficacy of various drugs used to achieve and maintain sterile urine in SCI patients. This study: 1) determined the relative effectiveness of Bactrim, Macrodantin, Hiprex, NegGram, and ascorbic acid in preventing UTIs in SCI patients; and 2) determined whether treatment with any of the aforementioned drugs is superior to "no treatment" with regard to the prevention of UTI in SCI patients.

Progress — SCI patients with neurogenic bladder constituted the study population. Neurologic level and extent of lesion were documented. Upon entering the study, a urine culture, colony count, and sensitivity were obtained and appropriate antibiotic therapy initiated. After sterile urine was achieved, subjects were assigned (by ordered sequence) to one of five prophylactic treatment regimens.

Cultures, colony counts, and sensitivities were obtained weekly while the patient was hospitalized. A specific study was discontinued if and when it became necessary to replace the indwelling catheter, if the patient became reinfected, or if continued follow-up became impractical. The mean and median weeks each patient remained infection-free were calculated and the differences between each drug's ability to maintain sterile urine were measured. Changes in bacterial sensitivities to the various drugs during prophylactic administration also were determined.

Bactrim was shown to be most effective in preventing urinary tract infection in SCI patients; ascorbic acid was least effective. However, it should be noted the median infection-free period was only 15 days for Bactrim and differences between drug groups were not statistically significant. Current evidence suggests that none of the drugs tested, including Bactrim, was particularly useful in preventing urinary tract infections in SCI patients at the doses studied.

In 47 patients experiencing relapses of urinary tract infections (reinfection by the same organism that was present prior to placement on a prophylactic microbial), there were 28 infecting organisms which lost sensitivity to antibiotics to which they were originally susceptible and 16 infecting organisms which became sensitive to drugs to which they were originally resistant.

Differential Renal Function in Patients with Neurogenic Bladder

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Purpose — Renal scintigraphy has been proposed as an appropriate procedure for routine measurement of renal function in many kinds of patients, including those receiving renal transplants and those with spinal cord injuries. This test offers several advantages over intravenous pyelography, the more traditional test for long-term renal follow-up. These advantages include lower radiation exposure, less patient preparation (no dehydration or bowel evacuation), no side effects, increased patient acceptance, and quantification of renal function on a kidney-by-kidney basis. However, for this test to be acceptable it must be compared with an established standard. In this case the effective renal plasma flow (ERPF), measured by renal scintigraphy must be compared with PAH clearance, the established standard for evaluation of renal blood flow.

Progress — Seventeen male spinal cord injury patients had their ERPFs measured by I^{131} ortho-iodo-hippurate clearance during renal scintigraphy. They also had renal plasma flows measured by classic PAH clearance tests utilizing ureteral catheterization for urine collection from each individual kidney.

The correlation coefficient between total ERPF (sum of flow to both kidneys) measured by renal scintigraphy and PAH clearance was 0.83 ($P<0.01$). The correlation between single kidney ERPF, measured by renal scintigraphy, and single kidney PAH clearance was 0.79 ($P<0.01$). We conclude from this study that individual kidney and total ERPFs as determined using scintigraphic techniques are a valid estimate of renal blood flow to individual kidneys and of total blood flow.

Determinants of Renal Function Alterations During Long-Term Follow-up in Patients with Spinal Cord Dysfunction Using Radionuclide Procedures

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Purpose — The neurogenic bladder and its associated complications often result in renal disease and ultimately renal failure, a leading cause of death following spinal cord injury (SCI). Thus, the study, a long-term evaluation of the urinary tract in SCI patients is needed: 1) to verify or disprove current impressions that minimal or modest anatomic changes demonstrated by excretory urography (EXU) are not clinically significant if unaccompanied by functional alterations detected by comprehensive renal scintigraphy procedures (CRSP); 2) to establish "baseline" CRSP parameters for SCI patients; and 3) to develop a reproducible diagnostic procedure with the capability of serving as an early indicator of impending renal deterioration.

Progress — SCI patients underwent CRSPs and/or EXUs as well as other appropriate diagnostic procedures and tests such as creatinine clearance measurements. The findings were evaluated statistically. Glomerular filtration rate (GFR) was determined scintigraphically.

Over 2,300 CRSPs were performed. Expected baseline values for CRSP parameters were established for SCI patients and normal controls and the effects of age, gender, and spinal cord status determined. CRSP-IVP comparisons revealed that virtually all significant upper tract deterioration found by IVP was accompanied by renal scan abnormalities, most notably effective renal plasma flow (ERPF). Renal stones and decreases in year to year ERPF measurements and episodes of chills and fever (presumably pyelonephritis) were found to be significant predictors for the development of pyelocaliectasis. In the absence of these factors, renal function is well preserved in most SCI patients, at least for up to 10 years post-injury. Minimal IVP changes are often transient and are not considered to be clinically significant unless ERPFs are concomitantly reduced. Renal scintigraphy is currently our procedure of choice for acute and chronic evaluation of renal function.

A Practical Method of Relaxing the Neck of the Bladder and the External Sphincter of the Urethra Which Permits Voiding in Paraplegic Cats

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — It was previously reported that in paraplegic cats all the reflex responses characteristic of a flexor reflex could be demonstrated by recording motor nerve electrical activity in the pudendal nerve branch, which supplies the external urethral sphincter (EUS). We also found that in paraplegic rats single motor unit EMG activity in the external anal sphincter was similar and roughly parallel to that in the hindlimb flexor muscles. This suggested that limb muscle reflexes might be evoked to inhibit EUS overactivity (which occurs in paraplegia and many spinal injuries) if the pudendal nerve on one side had previously been severed, leaving the EUS under unilateral reflex control.

We now report that we have induced micturition in paraplegic cats by

performing limb maneuvers that evoke reflexes inhibitory to the motoneurons supplying the EUS on the innervated side.

Progress — Under ether anesthesia the spinal cords of cats of either sex were transected at the mid-thoracic level by extra-dural ligation. A 3-5 mm segment of the right pudendal nerve was extirpated, leaving the EUS innervated only on the left. On the following day the animals were continent, and they had not voided. Fluoroscopic examination revealed an overfull bladder and a closed EUS. Manual pressure on the bladder did not overcome EUS resistance to urine flow.

The following maneuvers, all inhibitory to motoneurons supplying flexor muscles in the left hindlimb, were performed: 1) left hindlimb was placed in full flexion, stretching the extensors and reflexly causing inhibition of the motoneurons supplying the left side of the EUS; 2) right hindlimb was placed in full extension, stretching the flexors and causing crossed inhibition of the motoneurons supplying the left side of the EUS; and 3) footpad of right hindlimb was pinched, evoking a crossed extension reflex of the left hindlimb and crossed inhibition of the motoneurons supplying the left side of the EUS. On fluoroscopic examination these maneuvers caused relaxation of the bladder neck, and when the bladder was squeezed, urine was seen to pass freely down the urethra.

Although this approach solves the problems caused by spasm of the external sphincter, active contraction of the bladder (induced at the same time) would be of further advantage in obtaining complete emptying of the bladder.

Development of Analytical and Laboratory Models of the Bladder and Urinary Tract

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Sponsor: VA Hospital of Little Rock

Purpose — The main objectives of this research are: 1) design and construct a device to be implanted in a dog that will apply pressure to the bladder and force the dog to urinate (it must be possible to activate the device externally without having any part of the device pass through the skin); and 2) develop analytical and laboratory models of the bladder, urethra, and urinary tract.

Progress — A preliminary design has been completed for a device that can squeeze a dog's bladder hard enough to overcome the resting urethral pressure. The device will allow doctors to measure the bladder pressure required to force open the muscular valves in the urethra. The central component consists of a bladder cover and inflatable inserts that can be wrapped around the bladder. A pump placed in the scrotum can be activated externally and moves fluid from a reservoir placed in the belly to the inserts in the cover. The inflated inserts apply pressure to the bladder. In order to relax the bladder after voiding, one can press a release valve in the pump, allowing the fluid to return to the reservoir.

A number of improvements to the current design are being considered. New materials and attachment methods are being investigated which will allow the device to be installed more quickly and securely. New arrangements for the inflatable inserts, which will apply more uniform pressure, are also being investigated.

Analytical and Physical Model

The objective of this part of the research has been to study the fluid mechanics which occur in the lower urinary tract of a dog; namely, the bladder, the internal sphincter, external sphincter, and the urethra. This objective is accomplished in two ways. First, a mathematical model is being constructed using the finite element method to model both the flow of urine and the reaction of the tissues to that flow. Second, a physical model is being designed and will be constructed to provide data for comparison to results from the mathematical model.

A preliminary search of the literature has shown that physical modeling has been attempted by various investigators and these physical models have been compared and analyzed. Various physical models of the bladder have been developed while very few mathematical models have been completed. Because of this, extra time and effort have been put into the development of the mathematical model, and at this time, that development has been concluded. The bladder neck and the muscles involved in micturition have been modeled using the finite element method. The finite element methods are useful in structures and fluid flow because various parameters can be inserted into the elements so as to model that particular element in a more accurate manner rather than a sweeping generalization. Furthermore, various points along the bladder wall and within the fluid flow may be checked. This is more convenient than at the boundary conditions.

The development of the program has proceeded to the point of modeling the contracted external sphincter valve by stiffening one segment of the model and observing the results. Furthermore, the model is able to produce a zero pressure difference at a specific location in the urethral so as to simulate the actual physical phenomenon which occurs in the urethra.

Bronchial Mucus Secretion in Acute Quadriplegia: A Qualitative Study

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Purpose — The major cause of sickness and death among acute quadriplegic patients is paralysis of important breathing muscles. Within one to two days of injury it is common to observe the onset of pulmonary secretions copious in amount and of a nature unlikely to be due merely to failure of clearance mechanisms. The consequences of excessive mucus in airways are increased resistance to airflow, increased work of breathing and maldistribution of each breath and the clinical consequences may be low blood oxygen levels, elevated blood carbon dioxide levels and recurrent collapse of parts of the lung. In addition, the retained secretions predispose the patients to recurrent pneumonia. Many patients have to undergo numerous therapeutic bronchoscopies at which we always find tenacious secretions in copious amounts the removal of which usually results in re-expansion of the affected regions.

The problem is perplexing in many ways. It occurs in about 20 to 25 percent of acute quadriplegic patients; non-smokers and smokers alike. It has been suggested that mucus hypersecretion occurs as a result of unopposed tone in the vagus nerve that supplies airways because, at the time of cervical spinal cord injury, the counterbalancing nerve, the sympathetic, is injured. Yet, if the patient survives,

the problem may virtually disappear after several months although the traumatic sympathectomy is permanent. The fact that it is spontaneously reversible implies that it is not due to irrevocable structural change in the airways and that it may be amenable to treatment.

Progress — We plan to study all of these patients. At present, no data are available in the literature concerning which patients may develop mucus hypersecretion. A number of factors play a role in the pathogenesis of the hypersecretion and we are maintaining a clinical database on each patient including sex, chest trauma during accident, level of injury, respiratory status before injury, smoking history, occupational history, cardiovascular disease, presence of an endotracheal tube, tracheostomy, etc.

We follow the day-to-day clinical course of all the patients and try to relate this to the respiratory system. Of particular relevance to our study is the development of lung collapse or pneumonia. These will be assessed in the usual manner by physical examination, from the chest X-ray (taken routinely), cultures of the aspirated bronchial mucus, pulmonary function tests and from measurement of blood oxygen and carbon dioxide levels, as indicated.

We anticipate in about a third of these patients (i.e. eight to ten per year) bronchial mucus will need to be aspirated on numerous occasions and will provide adequate material for all examinations as well as providing reserve for later special studies.

Our plan is to carry out a detailed analysis of the mucus produced in the lungs of quadriplegic patients in the immediate post-injury period. Our laboratory is set up to provide state-of-the-art information about the physical and chemical properties of the mucus which we obtain. The methods used are technical and complex since mucus is a complex mixture of several types of large molecules. Several important questions are being addressed. What is the nature of the mucus observed in quadriplegia? Is it always the same type? Is it amenable to treatment? As the exessive mucus wanes, does its chemical composition change? Based on our experience with other diseases, such characterizations of the mucus will help in the choice of a potential therapy and help to reduce the morbidity and mortality associated with acute quadriplegia.

Control of Respiratory Skeletal and Smooth Muscle

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Sponsor: National Institutes of Health

Purpose — Alveolar ventilation is regulated by systems that control both respiratory skeletal muscle activity and airway smooth muscle tone. The overall objective of the proposed program is to examine respiratory skeletal and smooth muscle control at the receptor, effector, and central nervous system levels.

The program consists of seven projects: 1) central regulation of respiration and circulation; 2) respiratory sensation and control of breathing; 3) neuromuscular control of breathing in human infants; 4) chemical regulation of breathing during sleep and wakefulness; 5) neuromuscular control of breathing in enzyme-induced lung disease; 6) control of airway smooth muscle and its effect on breathing; and 7) chest wall mechanics and regulation of respiratory muscle activity. These

projects will specifically investigate: 1) the interplay of neural and chemical control systems in determining respiratory skeletal muscle activity and airway smooth muscle tone in adult and infant humans and in animals; 2) the effects of higher brain centers and states of consciousness of this interaction; and 3) the capacity of respiratory control systems to compensate for changes in respiratory skeletal muscle strength, endurance and coordination produced by lung diseases.

Basic data will be obtained on the organization and operation of the respiratory controller and its interaction with other control systems. These data will be used to develop mathematical models to provide new insights into controller function. Additionally, the studies have been designed to identify mechanisms and risk factors for respiratory failure that will be useful in devising and evaluating therapeutic interventions.

Effect of Body Position on Total Lung Compliance in the Traumatic Quadriplegic

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Sponsor: National Institute of Handicapped Research

Purpose — Since extended periods of immobility can result in reduced respiratory efficiency and development of respiratory complications, the addition of respiratory muscle paralysis such as that resulting from spinal cord injury (SCI) increases the likelihood of potentially life-threatening complications or a protracted period of rehabilitation for SCI patients. For some time there has been a need for research culminating in development of a "product," in this case a "formula" that can be followed for the optimal delivery of intermittent positive pressure breathing (IPPB) therapy to enable the clinician to redirect attention to other aspects of the patient's respiratory management.

Progress — This study: 1) determined optimal procedures for measuring inspiratory volume and total respiratory compliance in quadriplegics; 2) determined whether stable end-expiratory volume can be achieved during rest in different body positions in quadriplegics; 3) measured and documented end-tidal CO2 on subjects using a proposed IPPB method to determine optimal range of inhaled pressures; 4) determined optimal IPPB flow rate for quadriplegics in a variety of body positions; and 5) measured and documented total respiratory compliance by the method of Cherniack and Brown and the end-tidal CO2 achieved via IPPB treatment on normal subjects and quadriplegics.

An instrument system capable of making required respiratory measurements was configured and validated. Pilot studies on end-tidal CO2 during IPPB treatment were conducted on control and experimental subjects. Subsequently, controlled experiments to determine total respiratory compliance were performed with subjects in the supine, seated, and 20 degree, head-down positions. Inspiratory volume measurements were repeated with subjects in positions described utilizing a spirometer. Total respiratory compliance was measured, in the specified body positions, via the method of Cherniack and Brown. End-tidal CO2 was measured, in the specified body positions, with a Bird's IPPB respirator. The "best" total respiratory compliance (via the method of Cherniack and Brown) and the ideal end-tidal CO2 during IPPB were determined. The data were analyzed using an analysis of variance for repeated measures.

Results — The difference in total lung compliance between quadriplegics and controls was of borderline statistical significance ($p=0.095$). The effect of pressure was statistically significant ($p=0.02$), with maximum compliance for both quadriplegics and controls occurring at four cm H20. No differences were observed among positions, and there were no significant interactions.

Controls had significantly higher inspiratory volumes than quadriplegics at all pressures and positions ($p=0.02$). The main effects of pressure ($p=0.21$) and position ($p=0.16$) were not significant, possibly due to the study population's small size. However, there were two statistically significant interactions: 1) in the controls, inspiratory volume increased as pressure increased, but among quadriplegics, inspiratory volume decreased as pressure increased ($p < 0.0001$); 2) in the quadriplegics, inspiratory volume was consistently lower when patients were placed in the sitting position. In controls, inspiratory volume was generally highest when the subject was in a sitting position ($p=0.017$).

Increasing pressures during IPPB led to a statistically significant reduction in end-tidal CO2 ($p=0.003$). Although quadriplegics had consistently higher end-tidal CO2 values than controls in all positions and at all pressures, the differences were not statistically significant, possibly due to the small size of the study population.

High Frequency Jet Ventilation in Patients with Spinal Cord Dysfunction: A Study of Patients with Respiratory Insufficiency Secondary to Cervical Lesions

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Sponsor: National Institute of Handicapped Research

Purpose — Patients with spinal cord dysfunction who are dependent on current mechanical methods of artificial ventilatory support cannot speak because of the need for a cuffed tracheostomy tube. Such patients have fixed ventilatory patterns that frequently do not allow for short-term adjustments in ventilation to meet transient subjective alterations in sensations of dyspnea. Thus, a need exists to develop a ventilatory technology enabling the patient to speak and use whatever intrinsic ventilatory abilities are present to meet subjective needs, while simultaneously meeting physiologic gas exchange requirements via a reliable, simple system appropriate for home use.

Progress — In this study we are: 1) determining validity and reliability of transcutaneous 02 and CO2 monitoring in quadriplegics; 2) developing and testing a transtracheal ventilation device; 3) determining specific operating characteristics of a high frequency jet ventilation (HFJV) device in quadriplegics via testing with a multi-function jet ventilator prototype; 4) finalizing design and assembly of a HFJV prototype meeting specific requirements for a spinal cord dysfunction population; 5) conducting a multi-year trial of HFJV device(s) using transtracheal appliance(s) of varying designs; and 6) conducting multi-year outpatient reliability trials.

Data collection instruments for ventilatory monitoring, state of dyspnea, work of breathing, cough effectiveness, secretion mobilization, validation of transcutaneous 02 and CO2 monitoring, atelectasis and barotrauma have been developed. Ratios of transcutaneous gas values to arterial blood values and

correlation coefficients between transcutaneous and arterial blood gas values are being developed. A transtracheal appliance is being developed and tested. Optimal ventilatory frequency and effect of pulse volume (driving pressure and duty cycle) on oxygenation and carbon dioxide elimination and optimal positive and expiratory pressure are being determined. The system design is being revised continually and new HFJV devices are being assembled (as required) and assigned for patient use. Tracheal tolerance to HFJV with the transtracheal appliance is being determined. Data on effectiveness, complications, long-term operating reliability, incidence of mechanical/electrical malfunctions, and repair requirements are being analyzed.

Preliminary Results — An improved humidifier component has been developed and tested and the gas injector component simplified. A new transtracheal injector component also has been developed.

Future Plans — Due to the low number of patients who are prospective candidates for the high frequency jet ventilator, a decision has been made to relax the inclusionary criteria in hopes of increasing the size of the study population. Thus, entry criteria have been revised so that the study population will consist of consenting adults with chronic respiratory insufficiency resulting primarily from respiratory muscle chest wall dysfunction necessitating long-term, intermittent mechanical ventilatory support.

Pharmacokinetics of Drugs in Spinal Cord Injured Persons

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — Pharmacokinetics is a discipline that deals with events taking place upon the administration of a drug or chemical to a person. The absorption of the drug into the body, distribution of the drug between various tissues, and metabolism and excretion of the drug by the liver are all part of the specific behavior characteristics of a drug in a particular individual.

From the moment of onset, medications play a major role in the management of persons with spinal cord injury. However, little is known about how the spinal cord injured person's body deals with even the simplest of pharmacologic agents (in contrast to persons with kidney or liver disorders or pediatric and geriatric populations). Following spinal cord injury, alterations have been observed in normal physiologic, metabolic, and endocrine functions. Therefore, one might expect changes in drug pharmacokinetics in individuals with spinal cord injuries. These changes can alter body levels of a drug resulting in either decreased therapeutic benefit or toxicity to the patient.

The primary aim of this investigation is to determine whether or not the pharmacokinetics of certain drugs differ in spinal cord injured patients compared to non-spinal cord injured population.

Progress — The initial investigations examine the pharmacokinetics of a class of antibiotics (the aminoglycosides) widely used in hospitalized patients with spinal cord injury. These antibiotics represent an important class of agents where the

administered dose must be carefully controlled to avoid toxicity and maximize benefits. Too high a blood level of the antibiotic can result in hearing and kidney damage. Blood levels that are too low can make an infection difficult to control. The study will examine the pharmacokinetics of each antibiotic following intravenous and intramuscular routes of administration. If these studies indicate that aminoglycoside absorption and disposition in a patient with spinal cord injury is different from that in a non-spinal cord injured patient, then recommendations as to the best way to dose the drugs will be made.

Further studies will examine the absorption, distribution, and metabolism of an anti-spastic drug, Dantrolene, in patients with spinal cord injury. Studies in able-bodied persons suggest that Dantrolene is slowly and incompletely absorbed following an oral dose. This raises the possibility that the high doses frequently prescribed for spinal cord injury may not produce the desirable therapeutic benefits. The investigation will examine the absorption and metabolism of dantrolene as a function of dose and route of administration in spinal cord injured subjects and compare the results of the oral route of administration with the data obtained in able-bodied volunteers.

The result of these studies and subsequent investigations should greatly add to the body of knowledge concerning the therapeutic use of drugs in the spinal cord injured population and result in the ability of clinicians to expand individualization of drug dosage regimen to this patient group.

Actions and Metabolism of TRH in the Spinal Cord

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Purpose — Most spinal cord injuries resulting in the permanent loss of sensory and motor functions do not involve transection of the spinal cord, but rather contusion or compression of the cord. During the first several hours after contusion or compression, impulse generation and conduction ceases, blood flow to the injured segment decreases, and the consequent ischemic hypoxia triggers extensive tissue destruction. The initial anatomic integrity of the cord observed after injury, however, suggests that recovery could be facilitated if an appropriate therapy was aimed at: 1) supporting the anatomic integrity of surviving spinal neurons; 2) enhancing blood flow within the injured spinal segments; and 3) preventing the ischemia-related tissue degeneration.

Recent neurobiological researchers have shown not only the existence of a variety of neuropeptides and their receptors in the spinal cord, but also their participation in spinal cord physiology. This has opened the possibility of using endogenous neuropeptides as drugs for augmenting nerve regeneration and the recovery from injury. For example, Thyrotropin-releasing hormone (TRH) has been shown to produce an increase in skeletal muscle tones in several species, probably by a direct action on spinal motoneurons, to activate serotoninergic receptors in lumbar spinal cord, and to potentiate neurologic recovery after spinal trauma in cats. TRH is a hypothalmic peptide that has been shown by us and others to exist both in the rodent and in the primate spinal cord. More recently, this investigator has characterized for the first time the nature of a stereospecific high-affinity receptor for TRH in the rat spinal cord.

The user of peptides such as TRH as drugs is confronted with at least two basic problems: a) their rapid metabolis by tissues and body fluids; and b) the development of receptor subsensitivity or desensitization after prolonged treatment. To make a peptide an effective drug, the investigator must devise ways to circumvent these problems.

Progress — The present research goal of Dr. Prasad's laboratory is to find means to attenuate both TRH metabolism and the development of spinal cord TRH-receptor desensitization. The maximal diminution in *in vitro* TRH metabolism is achieved by two types of experiments. First, a number of analogues of TRH are screened and those exhibiting good affinity for spinal cord TRH-receptor but resistance to metabolism by endogenous peptidases will be selected. Second, an attempt is made to decrease the *in vivo* activity of TRH-metabolizing enzymes using various pharmacologic agents. Towards attenuating the down-regulation of spinal cord TRH-receptor by TRH, potential effects of glucocorticoids, hydergine, and propylthiouracil on receptor down regulation will be evaluated. These three pharmacologic agents were selected for this study because they are known to upregulate TRH-receptors in the brain and the pituitary gland. Having achieved these goals, the researchers will attempt to study the effect of the TRH-analogues on recovery from spinal cord injury in experimental animals.

Effects of Spinal Cord Injury on Drug Metabolism

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Purpose — The pharmacokinetics of medications administered to spinal cord injured (SCI) patients have not been widely investigated. There are numerous reports regarding alterations of normal physiological, neurological, and biochemical functions in the SCI population which raise the possibility that one or more aspects of drug distribution, metabolism, and excretion may be altered in this group. The overall objective of this research is to investigate in a systematic faction a number of representative drugs commonly used at various times throughout the life of SCI patients.

Progress — Ten subjects with SCI who were to receive tobramycin either prophylactically prior to a urological procedure or to treat infection were given an explanation of the research project and gave written informed consent. All subjects had normal renal function as evidenced by creatinine clearance measurements. Eighty milligrams of tobramycin were infused intravenously by a pump over a 60-minute period. Serum samples were collected before the infusion and at 30, 60, 75, 90, 120, 150, 180, 240, 360, and 480 minutes after the start of the infusion. Serum samples were assayed for tobramycin by the EMIT method of analysis. Data were analyzed by model-independent pharmacokinetic methods.

The mean age of our subjects was 28 years (range 18 to 54), the mean weight was 65 kg (range 45.5 to 82.7), and level of injury was from T4 to C3.

Following the infusion peak, tobramycin in serum concentration averaged $3.46 +/- 0.52$ g/ml. At the end of the 8-hour dosing interval, trough levels averaged $0.26 +/-$ g/ml.

In the ten subjects studied, the mean half-life of tobramycine was 121 +/− minutes. The serum clearance (C1) averaged 155 +/− 50 ml/min or 2.45 +/− 0.69 ml/min./kg. The volume distribution at steady-state (V_{ss}) averaged 27.3 +/− 5.7 liters or .043 +/− 1/kg.

The data in the limited population studied strongly suggest that the disposition of tobramycin in persons with SCI may be quite different than in people with intact spinal cords. Both the volume distribution (V_{ss} and clearance (C1) appear to be higher in SC1. Data published for tobramycin in the intact spinal cord subject indicates average clearance values of approximately 1.87 ml/min/kg and a mean volume of distribution of 0.26 l/kg. The physiological basis for the differences are not known, but these data suggest that dosages of tobramycin in patients with SC1 requiring aminogylcoside therapy may have to be increased to provide serum concentrations to adequately cover susceptible organisms. Trough serum tobramycin concentrations were <0.30 g/ml. If one assumes that trough tobramycin serum levels should be approximately 1 g/ml, we found that in our study population the aminoglycoside concentration falls below this level at four hours post-dosing. Thus, a change in tobramycin dosage regimen in SC1 patients would be appropriate.

Factors Affecting Sodium and Water Homeostasis in Spinal Cord Injury

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Purpose — Several clinical entities are common to the spinal cord injured patient including abnormalities in salt balance, hypotension, and hyponatremia. The thrust of this research is directed towards a careful clinical assessment of factors which alter ambient levels of aldosterone and/or its precursors as well as clarifying the controlling influences of antidiuretic hormone release. It is hoped that this information will facilitate the development of new treatment strategies for hypotension and states of salt imbalance as related to both aldosterone and antidiuretic hormone.

Progress — The goal of assessing the effect of provocative stimuli on either the release/inhibition of hormonal entry into the circulation is readily accomplished with existing methodologies. This research proposal will examine a number of different tests capable of altering the release of aldosterone. These include the response of aldosterone to metoclopramide (Reglan^{R}-dopaminergic inhibitor), ACTH, angiotension II and head-up tilting. All of these tests utilize substances which are intrinsic to the body with the quantity of the test substance administered being similar to that achieved *in vivo* by the SCI patient. This testing is performed over several days with careful attention to the sodium and potassium content of the diet as well as to the body position in which the study is performed. Once the test substance has been administered, blood samples are obtained serially over two to three hours to determine the pattern of release of the particular hormone under study.

The release of antidiuretic hormone will be examined in the setting of head-up tilting, water-loading, overnight dehydration and following the administration of ethanol or hypertonic saline. All of these are proven stimulators/inhibitors of

antidiuretic hormone release and mimic aspects of antidiuretic hormone metabolism to which the SCI patient is exposed in his/her daily activities. The pattern of release of antidiuretic hormone will be determined by repetitive blood sampling. The information from this study phase is to be employed in the eventual determination of optimal fluid intake patterns for the SCI patient.

Regardless of the extent of abnormalities in antidiuretic hormone metabolism that may be discovered, they will not lead to a state of dilutional hyponatremia unless substantial fluid intake has transpired. Since hyponatremia does occur with some degree of frequency in the SCI patient, it is apparent that water intake occurs to a degree sufficient for the evolution of this process.

To this end, an as of yet unexplored area of water metabolism, thirst, will be investigated. This facet of these research studies involves characterization of the thirst response to a number of infused solutes (glucose, saline, urea). These data may substantiate the clinical observation that a number of SCI patients manifest disordered thirst regulation. This regulatory defect in thirst is such that many SCI patients routinely ingest from four to six liters of fluid daily without any significant degree of encouragement.

It is hoped that by establishing this hormonal profile in the SCI patient that a clearer understanding of both salt balance and blood pressure control may be gained. It is hoped that additional information acquired will facilitate more effective preventive strategies to avert disturbances of water metabolism.

Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury: Determination of an Optimal Treatment Schedule

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Purpose — Heterotopic ossification (H.O.) following spinal cord injury (SCI) or several other severe neurologic injuries and diseases can limit joint motion and exacerbate the disability, possibly impairing function and limiting ambulation or wheelchair independence to the extent the patient must remain bedfast. Recently, however, a drug, Didronel (etidronate disodium), has been shown effective in preventing H.O. when administered prophylactically after SCI.

This study seeks to: 1)determine the optimal time post-injury Didronel therapy should be initiated to achieve the maximal prophylactic effect; 2) determine the optimal duration of Didronel therapy for maximal prophylactic effect; and 3) establish dosage-administration recommendations for Didronel that are capable of yielding maximal prophylactic effect.

Progress — The study population is being made up of patients admitted to the UAB-Spinal Cord Injury Care System between 0 and 120 days post-injury, whose lesions are neurologically complete (or neurologically incomplete with residual function less than a Frankel Classification of "motor non-functional"), who are at least 16 years of age and who are not pregnant. Patients in the series are subcategorized into early and late treatment groups and further divided into three- and six-month administration groups. X-ray films of both hips are obtained one day prior to initiation of Didronel therapy, at the end of each treatment period, and at one year post-injury.

Preliminary Results — As of December 31, 1984, 121 patient/subjects had been entered into the study. Substantially more patient/subjects (n = 79) were entered into the early treatment groups (15-44 days post-injury) than patient/subjects (n = 42) into the late treatment groups (45-120 days post-injury).

The major problem has been the high dropout rate. Of 121 patient/subjects entered into the study, 65 have been dropped from the protocol, primarily for reasons beyond our control. Reasons for being dropped include, but are not restricted to, losses to follow-up, inappropriate number of drug treatment days, deaths within one year of injury, failure to acquire X-rays at the end of drug treatment, and development of clinically significant heterotopic ossification requiring continued drug treatment for at least one year.

Our preliminary results are based upon the remaining 56 patient/subjects with complete data. Three patient/subjects developed minimal heterotopic ossification while still undergoing drug treatment. Eight patient/subjects developed heterotopic ossification after drug termination. Our provisional conclusions are that early treatment is superior to late treatment, and that treatment for 180 days may be no more advantageous than treatment for 90 days.

Presently, the active study population consists of 73 patients who remain on the protocol and appear capable of and willing to be followed post-discharge. Seven patient/subjects have completed the drug treatment phase but have an annual follow-up examination pending. Ten patient/subjects are currently completing the drug treatment phase.

Future Plans — This project was originally scheduled to be completed in May, 1985. However, because of the dropout rate, we have not achieved our target of 100 patient/subjects with complete data. Therefore, we have extended this project through May, 1988 or until our target is reached, whichever comes first.

A Laboratory Test to Predict and Monitor Bone and Skin Related Complications in Spinal Cord Injured Patients

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Progress — The project starting date was August 1, 1984. Up to January 7, 1985, we have recruited 33 new patients into the project, 23 cervical spinal injuries and 10 thoracic spinal injuries. We also have done seven follow-up determinations on some of the patients from our pilot project and some of the first patients in the present project. We have eliminated four patients from the study: of the four one patient was given Na Etidronte, another one was given steroids, and another one was eventually diagnosed as incomplete and was walking with braces. This left us with 19 patients in the study.

We have started reviewing the medical charts to assess the possible temporal relationship between the appearance of clinical symptoms of bone and skin related complications and the urinary concentration of galactosyl hydroxylysine (gal Hyl) and glucosyl-galactosyl hydroxylysine (glu-gal Hyl), respectively. We have completed these chart reviews on less than half in the project according to the presence or absence of bone or skin related complications. Nevertheless, among the eight patients injured less than six months (whose charts were reviewed), there

were only two without any manifest complications. Five patients had skin breakdowns of varying severity and one patient had developed osteoarthritis of the cervical spine.

We are continuing to recruit acute spinal cord injury patients and to review their charts. In the following six months, we should be able to obtain urine samples from the patients coming back to the clinic for outpatient checkups and from patients readmitted to complete their rehabilitation program. The project is on schedule. We should have a large enough pool of acute patients and follow-up determinations by the end of the second year of this proposal, for valid statistical analysis.

Role of Antidiuretic Hormone in Cardiovascular Responses to Postural Change in Quadriplegic Subjects

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Purpose — The purpose of this study is to begin to examine the role of ADH in the orthostatic response in quadriplegics. In normal persons moving from a supine to an upright position the effect of gravity, which would otherwise cause blood to pool at one's feet and result in fainting, is counteracted by a reflex change in the cardiovascular system called the orthostatic reflex. This response is orchestrated by certain sites in the brain and the effects on the cardiovascular system are produced by a highly patterned and selective activation of the sympathetic nervous system, as mediated by nerve tracts traveling in the spinal cord.

In quadriplegic patients the spinal cord is functionally disconnected from the brain: thus, because of damage to the descending nerve tracts exerting control on the sympathetic nervous system, the orthostatic reflex cannot occur as it does in healthy individuals. When a quadriplegic is placed in a wheelchair or tilted head-up on a tilt table, his blood pressure decreases due to pooling of blood in the legs, and there is a great likelihood of fainting. However, following rehabilitation, quadriplegics can sit for hours without fainting.

Understanding the mechanism of this changed orthostatic response in quadriplegics should lead to more rapid and efficient rehabilitation therapies, enabling quadriplegics to adapt to wheelchairs in shorter periods of time. Also, therapies may be designed to deal with the persistent problem of orthostatic hypotension.

Available data indicate that the sympathetic nervous system, which usually produces this response, is not involved in the response in quadriplegics, and it has been suggested that the renin-angiotensin system takes over this function of blood pressure control. Renin, an enzyme released by the kidney, produces angiotensin which is a hormone that constricts blood vessels and thereby elevates blood pressure. Renin release is directly stimulated by a decrease in blood pressure, as well as other factors. Thus, when the normal orthostatic response is absent, as in quadriplegics, and blood pressure begins to fall when in a head-up position, the renin-angiotensin system is activated. However, it is presently unclear as to whether this is sufficient to maintain blood pressure in these subjects.

A third factor capable of elevating blood pressure and thus possibly involved in the orthostatic response in quadriplegics is antidiuretic hormone (ADH, also called vasopressin). Recent evidence shows that ADH is important in the

regulation of blood pressure, especially in the absence of cardiovascular reflexes mediated by the sympathetic nervous system. Thus, ADH may act as a backup system for the orthostatic reflex, and may take over this function in quadriplegics.

Quadriplegic subjects and healthy volunteers will be tilted head-up on a tilt table, and blood samples will be collected periodically. ADH, renin, and catecholamine levels will be measured in these samples to assess the effect of tilting on ADH, the renin-angiotensin system, and the sympathetic nervous system respectively. Blood pressure and heart rate also will be monitored, and changes in these parameters will be examined in relationship to changes in ADH, renin, and catecholamine levels. These studies should advance our understanding of the orthostatic reflex in quadriplegics and thus serve as a foundation from which to develop strategies to enhance this response in quadriplegics.

Prediction of Spared Motor Pathways and Recovery from Injury Using the Motor Evoked Potential in a Spinal Cord Impact Model

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Purpose — In the treatment of spinal cord injury the monitoring of the spinal cord's function is critical in the evaluation of treatment efforts. Surgery, involving the spinal cord or the surrounding bony structures, can give feedback to the surgeon as to whether his actions are causing harm so that he can formulate his strategies to best protect the spinal cord. There are two methods of monitoring spinal cord function. The first is the clinical examination, in which the patient follows commands from the physician. The second is an electrical test of the nervous system called the somatosensory evoked potential.

In the somatosensory evoked potential the stimulation of a nerve in the arm or leg results in electrical signals travelling up the spinal cord to the brain. These can be recorded by EEG equipment coupled with sensitive signal averaging computers to produce evoked potentials. It has been a very useful test and can be used on patients who are neither cooperative or awake, as well as those who are. However, it has been less useful than needed for good spinal cord injury care because it does not monitor the motor pathways. Instead, it monitors the dorsal columns in the posterior part of the spinal cord. Since they have a different blood supply as well as a different location and function from the motor pathways, it is not surprising that instances in both clinical and experimental literature have shown failure to predict motor weakness.

Progress — We have developed a motor evoked potential which was based initially on direct stimulation of the spinal cord when exposed during surgery. By stimulating over the area carrying the motor pathways and then recording the resulting electrical signal further along the spinal cord, we have produced a monitor of the motor system that was more accurate than the somatosensory evoked potential in determining the patient's strength after surgery.

To produce a less invasive model, we began stimulating the brain through the scalp and skull. In this method an electrode is placed on the scalp over the motor cortex and a second electrode placed in the subcranial location to direct current

down through the scalp and skull to the brain. We use the anterior hard palate. The current in the range of 30 milliamperes is applied for about one-half of a millisecond. This produces a firing of the large motor neurons in the motor cortex. Their resulting signal runs down axons in the spinal cord to the lower motor neurons, which are themselves fired, producing signals in the peripheral nerves of the arms and legs. This very weak signal can be picked up by signal averaging methods and tracked along the spinal cord and peripheral nerves. In studying it we can identify the functional status of the motor system and look for locations where the signal is blocked, weakened, or slowed.

Our investigational studies in animals have shown the signal to run primarily in the cortico-spinal pathways and in small ventral spinal cord motor tracts, including the anterior spinal tract. Other investigations have shown that these small ventral tracts are critical in both primates and cats for the recovery of basic walking function after injury. In injury studies with acute animals, we have found that the motor evoked potential is considerably more sensitive to injury than the somatosensory potential even though the injury occurs over the dorsal columns that carry the somatosensory potential.

We are beginning to study the effects of spinal cord injury in chronic animals with the specific purpose of identifying those parts of the motor evoked potential which run in the small ventral motor pathways and that are primarily responsible for recovery of ambulation after injury. We are replacing a recording electrode directly on the ventral spinal cord and identifying those components which are strongest there. We also are lesioning studies and looking for those components left in the ventral cord and then identifying them with a various statistical analysis and signal identification methods. We will then correlate those signal components that are in the ventral spinal cord with the animal's recovery function. We hope to find an index in the motor evoked potential that we can use to determine the status of a patient's spinal cord vis-a-vis walking. The index can be used to protect the spinal cord during surgery and to evaluate patients who arrive in the emergency room newly injured. It also can guide treatments used in helping spinal cord injured patients. In the laboratory it should help to best target the treatment toward those functions of the spinal cord that will result in ambulation.

Evaluation and Rehabilitation of Reproductive Function in Paraplegia

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Purpose — The overall goal of this research project is to develop and implement technology that will be useful in assisting the sexual rehabilitation of paraplegic patients as they strive to restore their normal functioning in society. Two specific objectives were established, one directed primarily toward instrumentation (electrostimulation and catheter modification), the other toward clinical utilization of this instrumentation and related clinical aspects of semen evaluation.

Progress — During the first six months of this research, eight patients were identified as possible project candidates. Their level of injury is between T4 and T12-L1. All were evaluated once using RPE, with accompanying assessment of the quality of semen obtained. Three subjects were selected for repeat RPE

procedures at three-week intervals. It is planned during the second half of the study period to increase the number of subjects to ten, with a greater percentage of these studied on a repeat basis.

Several specific topics are being addressed during this project, with answers at present remaining tentative pending further work. One formal investigative week with both Georgia-based (Martin, Warner) and Palo Alto-based (Perkash) workers took place, in December, with the three remaining week-long sessions planned for March, June, and July, 1985.

One topic involves final integration and miniaturization of the electrostimulation unit, with dial placement and inclusion of fail-safe current limiting devices designed for "user-friendly" operation. This has been done, and we have taught several medical personnel the details of how to utilize the equipment. Under the supervision of Dr. Perkash, they have gained experience in use of the equipment in carrying out the more than two-dozen stimulation sessions performed thus far. This personal interaction has improved the unit's ease of operation and led to improved protocols for semen collection. Continued experience will doubtless produce additional suggestions for an optimum stimulus protocol.

A second topic involves catheter-modification and fitting to ensure optimum capability for antegrade semen flow. Typically, we are finding that a #18 Foley 3-way catheter with balloon inflated between 20 and 30 cc is adequate, if carefully positioned, to prevent retrograde flow, thus allowing antegrade flow and collection. To this extent, we are finding that patients having had extensive surgical incision of the bladder neck (performed to improve voiding) typically do not permit as tight a seal of the Foley balloon catheter against the bladder floor, allowing retrograde semen flow during RPE. Thus, a suggestion may be to use care in such bladder neck surgery to ensure maximum improvement in voiding with minimum surgical alteration of the associated musculature. Otherwise, in such patients who desire collection and evaluation of their semen, the problems of dilution and acidification by bladder urine will be a confounding issue in evaluating their fertility status.

A third topic involves the effectiveness of repeat RPE on semen quality (sperm numbers, sperm motility, sperm morphology). While we find that semen collected by antegrade flow has better motility than that collected by retrograde flow into the bladder (morphology in both is similar), it appears that three-week intervals for repeat electrostimulation may be too frequent to permit replenishment of sperm stores. More data are required for confirmation of this. Results of testicular biopsy indicate a frequent occurrence ($\sim$50 percent) of mild testicular atrophy, which probably decreases the total number of sperm produced by the testis per unit time.

An additional topic involves the aggressive management of urinary tract infections in all patients studied, with a view toward minimizing possible deleterious effects of such infections on sperm motility. Typically, motility in collected semen is very low ($<$20 percent), and this poses a problem in the potential use of this semen for artificial insemination. It is well known that bacterial infection, as well as certain drugs used to minimize infection (such as mandelamine), are toxic to sperm survival. Thus, optimization of the health of the urinary tract will make it a less hostile environment for the temporary transit of sperm as they proceed from *vas deferens* through urethra upon ejaculation or emission.

A related topic involves the provision of an optimal environment for sperm survival. To enhance the survival rate of sperm directed into the bladder by retrograde flow, we are using several approaches: 1) flushing the bladder with a buffered solution prior to each RPE procedure; 2) leaving a very minimum residual volume of such buffered solution in the bladder prior to RPE to minimize dilution and ensure acceptable pH maintenance; and 3) immediate transfer of retrieved sperm to protein-containing buffered media similar to those used for *in vitro* fertilization.

Continued patient studies during the second half of this funded year should provide the additional experience and data required to improve the ease of semen collection using RPE and improve the motility of sperm obtained.

Diglycerides and Phosphatidic Acid in Peripheral Nerve and Spinal Cord During Wallerian Degeneration

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The term Wallerian degeneration is applied to the changes that occur after spinal cord injury or lesions of the brain. The segment of a nerve fiber that lies distal to the injury is subject to the degenerative process. In warm-blooded animals and man, Wallerian degeneration of a peripheral nerve is complete in about 50 days. In the spinal cord the process is relatively slow, requiring 200 to 300 days for completion. Wallerian degeneration in a peripheral nerve is reversible. When allowed to regenerate, a nerve will restore motion and sensation to a powerless limb. In contrast to this regenerative potential in the peripheral nervous system, functional recovery after spinal cord injury is sparse or absent. The reason for this difference has not been established.

The goal of research in Wallerian degeneration of nerve and spinal cord is the discovery of the molecular events that lead to degeneration. Hopefully, recognition will permit us to prevent or retard the degenerative process. With the limited regenerative potential of the spinal cord, prevention of Wallerian degeneration after the injury would appear an attainable goal. The induction of actual spinal cord regeneration may continue to elude us.

Wallerian degeneration is associated with biochemical changes in the degenerating nerve tissue. Many of these changes are already well characterized. Since the fatty envelope of nerve fibers, the myelin sheath, proceeds to total destruction during Wallerian degeneration, myelin lipids have been studied in greatest detail.

Even though no trace of the specific lipids of the myelin sheath may be found in a totally degenerated nerve, sprouting of new nerve fibers will result in reassembly of the myelin sheath and restoration of a near normal concentration of fatty substances. As may be predicted, such biochemical healing does not occur in the injured spinal cord.

Progress — In our laboratory, a specific aspect of lipid metabolism is being studied. It is the conversion of neutral lipids to phospholipids. Neutral lipids are molecules of relatively simple structure and contain glycerol (glycerin) and one, two, or three fatty acids. Among these lipids, the diglycerides containing glycerol

and two fatty acids are thought to be the most important because they are linked to the synthesis of phospholipids. Phospholipids are rather more complex than neutral lipids because they contain glycerol, fatty acids, phosphorus, and a base such as choline or ethanolamine, or the amino acid serine.

The exchange between diglycerids and phospholipids occurs by the sequence of enzymatic reactions. Diglyceride can go on to phosphatidylcholine (reaction 1) or return to phosphatidic acid (reaction 2). Reaction 2 counteracts reaction 1, perhaps providing an important balance between the tissue levels of diglyceride and phosphatidic acid. In Wallerian degeneration of the peripheral and central nervous systems, reaction 1 is accelerated, and more phosphatidylcholine is biosynthesized. However, the process is out of control and does not lead to proper assembly of the myelin sheath. The velocity of reaction 2 during Wallerian degeneration has not been studied. The enzyme that catalyzes reaction 2 (diglyceride kinase) is present in central nervous tissue but has not been examined in the peripheral nerve. It is proposed that this cycle of reactions is disturbed during nerve and spinal cord degeneration because reaction 1 is accelerated and reaction 2 slowed or absent. If the cyclical exchange between phosphatidic acid and diglyceride can be stabilized immediately after nerve or spinal cord injury, perhaps by a drug, the destructive process of Wallerian degeneration may be brought under control and chances for recovery may be enhanced.

Collagen Dysfunction in Quadriplegia

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Sponsor: National Institute of Handicapped Research and the Technology and Research Foundation of the Paralyzed Veterans of America

Purpose — This study seeks to elucidate the ways in which collagen metabolism is altered in spinal cord injury (SCI): what are the consequences of such alteration and what causes that alteration?

Project I: A method has been developed to measure hydroxylysine glycosides in an automated amino acid analyzer to establish the fact that increased concentration of a specific glycoside is an indication of the tissue origin of the collagen being degraded. It is hoped that physicians will be able to use this information to decide what preventive measures are of greatest importance for the individual patient and thus reduce the number of complications following SCI.

Project II: Density of adrenergic receptors in the insensitive skin of SCI patients is being measured by radioligand binding assays. The objective is to show that altered sympathetic responses lead to altered nutritional status of skin thus increasing its susceptibility to pressure damage.

Project III: The activity of the enzyme lysyl hydroxylase and the concentration of some amino acids characteristic of collagen are being measured in skin biopsies from above and below the injury in SCI patients. The objective is to show that SCI leads to abnormal enzyme activity which in turn leads to defective collagen biosynthesis and decreased tensile strength of the skin. If the specific defects in the collagen metabolism of SCI can be identified, they may be amenable to pharmacological intervention.

Progress — Project I: The data show that urinary excretion of both hydroxylysine glycosides is elevated immediately after the injury, reaches a peak between three

and six months after injury and returns to normal values about a year after injury. Patients with skin-related complications show a rise in glucosylgalactosyl hydroxylysine about one month prior to clinical manifestations. The relationship between urinary excretion of galactosyl hydroxylysine and bone-related complications is not as well documented yet.

Project II: Alpha adrenergic receptors show a trend towards a decrease in density with increasing time since injury. We hope to obtain enough data to achieve statistically significant results.

Project III: The lysyl hydroxylase activity assay has been tested, the effects of varying the concentrations of the several cofactors have been studied, and work on patient skin biopsies has begun.

Upon completion of these three projects, a clearer picture of the relationship of neurological deficit to somatic structural abnormalities in SCI should emerge.

Incidence and Clinical Significance of Impaired Brain Function in Spinal Cord Injury: A Continuing Preliminary Study

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Sponsor: National Institute of Handicapped Research

Purpose — Incidence statistics on concomitant brain impairment in spinal cord injury (SCI) patients are lacking. Such data are needed both in the individual case and in the aggregate so adequate planning and service offerings can be provided to patients who suffer this significant, associated injury.

This study is: 1) identifying, validating, and utilizing a battery of neuropsychological tests to diagnose impaired brain function in a series of recently injured SCI patients; 2) estimating the incidence of impaired brain function in recently injured SCI patients; and 3) determining whether neuropsychological assessment data correlate with demographic, epidemiologic, and medical data from the same series of SCI patients.

Progress — A neuropsychological test battery has been identified, evaluated for appropriateness/applicability and validity, and subsequently administered to newly admitted SCI patients. Medical, epidemiologic, and demographic data on all patients in the series are being reviewed retrospectively. All data, including neuropsychological test results, are being evaluated quantitatively and qualitatively. At the end of the data collection phase, summary data sheets will be presented to a panel of neuropsychologist judges who will not know the neurologic condition of the patients. Based upon their review of patient-specific data, they will attempt to diagnose probable brain pathology. The incidence of concomitant brain and spinal cord injury will be estimated and a determination made regarding predictive ability of neurological and descriptive measures. All data will be analyzed in an attempt to identify significant, meaningful correlations.

Preliminary Results — As of December, 1984, 99 patients completed initial test batteries and 25 of those completed repeat batteries. We are excluding patients who are psychotic, schizophrenic, those who have known premorbid organic brain impairments, and/or children under 16 years of age. We are performing medical record audits to acquire each patient's demographic data and to establish clinical

evidence of brain injury. A provisional inspection of our data suggests more impairment across a wider variety of cognitive tasks for a larger percentage of patients than originally anticipated.

An incidental but important by-product of this project has been the delineation of a comprehensive neuropsychological test battery suitable for use in a rehabilitation setting. No tests in this battery require hand function to complete; hence the battery can be used equally well by quadriplegic and paraplegic patients.

Incidence, Characteristics, and Clinical Significance of Anemia in Patients with Spinal Cord Dysfunction

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Sponsor: National Institute of Handicapped Research

Purpose — Anemia commonly develops within the first six months following spinal cord injury (SCI), even in the absence of detectable blood loss. Some clinicians order blood transfusions if the hemoglobin falls below 10-12 Gm percent. However, prevention is more desirable than treatment. Whether anemia is due to stress, inadequate nutrition, blood loss, depressed red blood cell (RBC) production, or increased RBC destruction has not been determined. Anemia may be an important factor in the development of secondary complications. It also may delay or prolong the rehabilitation program. Thus, finding the cause of anemia in this population is a requisite to its prevention.

This study will: 1) determine those epidemiologic and/or demographic variables that affect the duration and/or severity of anemia; 2) determine the natural history of changes in the hematologic profile of SCI patients; 3) establish the natural history of RBC kinetics after SCI; and 4) determine whether alterations in nutritional profile are associated with the incidence, duration, and/or severity of post-injury anemia.

Progress — The study population is being made up of a series of neurologically complete quadriplegics who did not receive blood transfusions following their SCI. Demographic characteristics and the hematologic correlates of the population are being documented as are basic hematologic profiles. Ferrokinetic studies also are being performed. Nutritional profiles and their hematologic correlates are being established. All data will be analyzed utilizing appropriate statistical techniques.

Preliminary Results — The project was initiated on June 1, 1984. As of December, 1984, six patients had been entered into the study. All patients were males between the ages of 19 and 26 whose neurologic levels of lesion were between C4 and C7. Erythropoietin quantitative assays were performed by the Bio-Science Laboratory in Van Nuys, California.

All six patients were evaluated at six weeks post-injury. They had erythropoietin values in the low normal range (4-14 milli-immunochemical units erythropoietin/ml serum). The normal reference values are 7-36 units/ml. Only two patients agreed to participate in the plasma volume and red cell mass studies using I-125 and Cr-51. These patients had a slightly lower red cell mass than normal but had higher plasma volumes. Total blood volume was increased in one patient and normal in the other. Total body hematocrit was also low.

Future Plans — Computer entry and preliminary analysis of data will begin in the next grant year. Interestingly, it appears that despite normal peripheral red cell, hematocrit and hemoglobin counts, the serum erythropoietin level is low during the acute stage of spinal cord injury. Shrinkage in red cell mass is also possible during this time period. We will explore these preliminary findings in considerable detail during the remaining year.

The Relationship of Nutritional Status and the Occurrence of Secondary Complications in Spinal Cord Injury Patients

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Sponsor: National Institute of Handicapped Research

Purpose — Nutritional requirements of the spinal cord injury (SCI) population are almost entirely a matter of speculation. There are many unanswered questions concerning protein requirements, lipid mobilization, and vitamin and mineral requirements.

This study seeks to: 1) determine the frequency of nutritional deficits in recently injured (viz. acute) SCI patients; 2) document secondary medical complications and examine the association between them and low or deficient nutritional parameters; 3) assess muscle mass, strength, and endurance as indicators of motor function, examining the association between these parameters and low or deficient nutritional parameters; 4) assess T and B lymphocyte numbers, cutaneous hypersensitivity, neutrophil bactericidal activity, and production of salivary IgA as indicators of immunologic function, examining the association between decreased immunologic function and low or deficient nutritional parameters; and 5) assess depression, self-concept, and anxiety as indicators of psychological functioning, examining the relationship between psychologic parameters and low or deficient nutritional parameters.

Progress — A series of 60 SCI patients with neurologically complete lesions, sensory sparing only, or non-functional motor capabilities who are between 15 and 60 years of age, without multiple fractures and without concomitant head injury is being studied throughout the course of hospitalization in the rehabilitation setting. Eventually, the series will include 30 patients with cervical injuries, 20 with lesions between T-1 and T-10, and ten with lesions below the tenth thoracic segment. A wide spectrum of nutritional variables is being measured at regular intervals. Nutritional deficiencies and secondary medical complications developing after admission are being documented and analyzed statistically. Muscle mass and work capacity are being determined and analyzed. Immune fractions are being determined at regular intervals after admission. Also, psychological evaluations are being performed at regular intervals after admission. Ultimately, all data will be analyzed and compared for the possible identification of association(s) between physiologic, psychologic, and nutritional parameters.

Preliminary Results — As of mid-December, 1984, data have been collected on 47 subjects. Twenty had cervical injuries, 14 had thoracic injuries at or above T-10, and 13 had injuries below the tenth thoracic segment.

Preliminary findings indicate that caloric intake was frequently less than 1000 calories/day for prolonged periods. Other values found frequently to be low include Vitamin A, carotene, folate, ascorbate, retinol-binding protein, transferrin, and albumin.

Allergy to mumps antigen, as reflected in delayed cutaneous hypersensitivity (DCH), was present in 87 percent of the patients, compared to 30 percent of healthy controls. Patients with low maximal inspiratory pressure (MIP) tended to have more nutrient deficiencies than those with normal MIP, and those with low maximal expiratory pressure (MEP) tended to have more nutrient deficiencies than patients with normal MEP.

Our early impressions are that nutrient deficiencies are common in the acute phase of SCI and may be associated with depressed immune response and muscle function.

Spinal Cord Injury Model

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Sponsor: National Institutes of Health

Progress — Based on our previous work in the laboratory, and that of other laboratories, we have selected two methods of injury for detailed analysis with respect to reproducibility and ability to grade the magnitude of lesion behaviorally, electrophysiologically, and morphologically. Having identified the mode of injury which best meets these criteria, this injury model will then be used for an evaluation of the effectiveness of six different treatment modalities. In order to characterize the lesion and its evolution, both longitudinal and serial observations will be made. In addition, an evaluation will be made of the relationship of treatment to intensity of injury.

Radiography and Radioisotopic Angiography of Spinal Cord

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Sponsor: National Institutes of Health

Purpose — Selective arteriography (radiographic) of the spinal cord is a diagnostic technique that has proven to be very informative in cases of arteriovenous malformation, tumor, obstructive vascular disease, trauma, and postradiation damage of the spinal cord.

Radioisotope angiography of the spinal cord offers distinct advantages as a screening method, and in certain types of intraspinal pathology may give information not available by any other diagnostic test.

Progress — Preliminary experience with new techniques, dynamic computed tomography (DCT), digital subtraction angiography (DSA), position emission tomography (PET), using 18F-2-deoxyglucose, and nuclear magnetic resonance imaging (MRI) of the spine indicates that these methods may be useful screening and follow-up procedures in the evaluation of certain vascular lesions and tumors of the spinal cord.

Reconstruction of One Level Cervical Spinal Instability (Dog)

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Sponsor: National Institutes of Health

Purpose — Rehabilitation from acute quadriplegia is frequently complicated by coexistent cervical spinal instability, in many cases secondary to ligamentous damage. Without surgery such injuries require bracing for three to six months often with the cumbersome halo-vest. Not only does this impede physical rehabilitation but even after its prolonged use, chronic spinal instability may still result. A variety of surgical procedures exist for reconstruction of the ligamentously unstable cervical spine. Few have a logical basis in preliminary research, but instead represent an individual's personal clinical experience and when attempted by others often have an unacceptable incidence of complication.

The purpose of this project is to develop a canine cervical ligamentous instability model.

Progress — Acute instability will be produced in a single spinal motion segment. Different general reconstructions will be applied to the model. The progression of instability in the model and the way in which the reconstructions alter it will be objectively studied by:

1) Serial Radiographs

2) Overload and, in some cases fatigue, flexion and extension mechanical testing using a Materials Test System—810 Unit to generate the following mechanical parameters:

a) Construct Shear and Angular stiffness, ultimate strength and energy absorption to failure.

b) Total Shear and Angulation to failure.

c) Number of cycles to failure for Constructs tested in fatigue.

d) Changing Construct stiffness as a function of number of cycles for Constructs tested in fatigue.

The above data will be statistically analyzed.

3) Histological slides of the interface between the reconstruction materials and the original spinal elements.

The above studies will be obtained (from different experimental animals) at monthly intervals postoperatively up to three months. A stability continuum for the different reconstructions will thus be created from which their strengths, weaknesses, and specific indications will be defined in a laboratory setting.

Standardized Reproducible Spinal Cord Injury Model (Mammals)

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Sponsor: National Institutes of Health

Purpose — This project will develop, test, and validate a standardized, reproducible spinal cord injury model in animals that is characterized in terms of the evolution of behavioral (functional), electrophysiological, and morphological changes arising as a result of the lesion with the primary intent of testing new therapeutic modalities for the treatment of spinal cord injury. The study is intended to demonstrate that such a model can be used for testing of new therapeutic approaches by utilizing it for evaluating medical therapies reputed to be useful in the treatment of spinal cord injury.

In the first phase of the project, we propose to determine the optimal impact conditions to establish three levels of injury (corresponding to 10 percent, 50 percent, and 90 percent residual functional deficit) using a weight-dropping device (open impact injury) in the rat.

Spinal Somesthetic Pathways (Human, Monkeys)

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Sponsor: National Institutes of Health

Purpose — The proposed studies have two major goals: 1) to improve neurological diagnosis of spinal cord injury by defining the sensory capacities that depend critically upon transmission along three major ascending pathways (in the ipsilateral dorsal column, the ipsilateral lateral column, and the contralateral ventral quadrant); and 2) to improve understanding of the participation of spinal cord circuitries in the control of elimination of pain. This is a multidisciplinary approach within the neurosciences, involving highly quantitative evaluation of sensory thresholds and motor reactions to precisely controlled somatosensory stimuli.

A variety of correlations will be made between anatomical manipulations (and measurements) and the occurrence of functional deficits. Careful attention will be directed to the capacity for recovery of function following spinal lesions. Pharmacological compounds will be introduced directly on the spinal cord to determine the importance of different descending spinal pathways and transmitter systems for inhibition of pain. Clearly defining the roles of serotonin, noradrenalin, and opiates on sensory coding and motor output at spinal levels is fundamental to understanding neural mechanisms of pain control, which should lead to new methods of pain therapy.

The proposed studies will be conducted with monkeys, because the pain conduction systems are quite similar among primates and very different between primates and other mammals. The pain stimuli are brief, non-injurious, and easily tolerated by monkeys and humans. Other stimuli will involve tactile and/or proprioceptive receptors and will test the most acuitive somatosensory functions involved in active touch or grasp of objects in the environment. Sensations of texture or resistance to pressure by the hands are crucial to the advanced manipulative skills of primates, and the proposed studies will delineate the spinal pathways involved in these functions.

National Acute Spinal Cord Injury Study (Human)

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Sponsor: National Institutes of Health

Purpose — The pharmacologic management of acute spinal cord injury in humans remains equivocal despite decades of animal clinical investigation. The National Acute Spinal Cord Injury Study (NASCIS) was established in 1977 to evaluate new treatment modalities using a multi-center randomized clinical trial (RCT) methodology. The first RCT (NASCIS I) was successfully completed in 1983.

Recent animal data suggest that high doses of methylprednisolone (30 mg/k) and naloxone (5 mg/k) may be efficacious in improving neurological recovery

after acute spinal cord injury. It is proposed to compare these drugs against placebo in a double blind RCT at 12 medical centers. The study protocols will be modified after existing ones already developed by the study group. Eligible spinal cord injury patients will be randomized to one of three treatment arms within 18 hours of injury. Standardized neurologic exams will be given on admission, 24, 48, and 72 hours, and six weeks, six months and one year after injury. Improvement in motor function, pinprick, light touch, and deep pressure sensation are the major study outcome measures. Morbidity and mortality, especially as they relate to drug treatment, will be monitored throughout the trial and studied in detail. A total of 480 patients will be randomized. Potential confounding and effect modifying factors will be examined and controlled using log linear models and logistic regression analyses.

The National Acute Spinal Cord Injury Study is one of the most detailed, standardized, and complete data sets of the management of acute spinal cord injury available. It also will be used, therefore, to test hypotheses concerning the potential advantages of surgical and other management procedures in improving neurological outcomes.

Spinal Cord Injury Research Center

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Sponsor: National Institutes of Health

Purpose — Spinal cord injury and its eventual outcome is a product of the cellular and molecular mechanisms of degeneration, growth, and regeneration. These processes may be best understood by a combination of studies that examine the acute and chronic mechanisms of degenerative phenomena. In addition, since the capacity to regenerate spinal neurons is limited in the adult spinal cord, an attempt to examine regenerative phenomena during development, when such phenomena are enhanced, is an important part of the proposed research. The specific aspects of these phenomena to be explored include an examination of: 1) the biochemical pathophysiology of degeneration; and 2) the physiology, biochemistry, and anatomical characterization of reorganization of nervous tissue subsequent to nerve trauma.

The further development and evaluation of a new injury device is an important step toward the control of injury as an independent variable. Alterations in lipids, membrane integrity and recovery, and the ability to induce changes in the metabolic (P02) or ion ($Ca++$) microenvironment will be studied to assess the effects of ischemia or impact injury to the spinal cord. Interventions into this pathological process also will be attempted with naloxone to improve tissue oxygenation and spinal hypocalcemia. The degree to which such interventions are successful also will be assessed chronically by behavioral or morphometric analysis.

Mechanisms of axolemmal synthesis are to be studied by assessing ganglioside contributions to peripheral nerve trauma. Reorganization and regenerative phenomena will be assessed in the cat and developing frog, respectively, using HRP histochemistry, intracellular neurophysiological techniques, and electron microscopy. The role of nerves in the regenerative plasticity involved in limb regeneration is also to be assessed. Only by studying acute alterations in spinal

pathophysiology and attempting to reverse them chronically can we begin to effect changes in the capacity of the central nervous system to use the inherent mechanisms of regeneration that it had, but may have lost, during development.

Clinical Research Center for Acute Spinal Cord Injuries

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Sponsor: National Institutes of Health

Purpose — The proposal for the continuation of the Clinical Research Center for Acute Spinal Cord Injuries at New York University will examine several interrelated hypotheses concerning the pathogenesis and treatment of spinal cord injury (SCI) at both the laboratory and clinical level. The major hypothesis to be tested is that the irreversible lesion resulting from injury to the spinal cord is neither immediate nor complete, and that appropriate therapy can be designed and instituted to ameliorate the multiple pathogenic mechanisms initiated by the trauma. Individual projects will look at innovative treatment regimens in experimental and clinical SCI. Information concerning the pathogenesis of SCI has been provided by the component projects of this proposal. We present three principal theories concerning the mechanisms by which trauma to the spinal cord may lead to irreversible damage.

The major emphasis of this proposal will be to test each of these hypotheses by themselves and for correlations that may suggest a common pathogenesis underlying more than one of them. The first concerns the role of endogenous opiate peptides in the damage to the spinal cord and the ability of the opiate antagonist, naloxone, to improve neurological recovery after SCI. The second deals with the causes of ischemia to the spinal cord, the effects of ischemia on the spinal cord, and methods available to prevent a decrease in spinal cord blood flow. The third hypothesis is that SCI initiates a series of pathologic free radical reactions that produce damage to critical biomembranes in the spinal cord. These pathologic reactions are amenable to control by specific pharmacologic methods. The concept of the development of an irreversible spinal cord lesion at some time after trauma carries with it the inherent view that the initial events are not sufficient by themselves to cause devitalization of tissue but require the progressive development of interrelated pathologic responses. It is to these latter events that therapy will be directed.

A Center for Acute Spinal Cord Injury

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Sponsor: National Institutes of Health

Progress — This program is a multidisciplinary approach to the problems of spinal cord injury (SCI). Included are: an epidemiological study of spinal cord injury in Connecticut with delineation of incidence, cause, evaluation of treatment; cost comparison of treatment in an organized SCI center and community hospitals in Connecticut, and determination of when stability of neurological function occurs; studies of animal models of spinal cord injury, evaluating various treatment modalities, effects of trauma on spinal cord blood flow, and metabolism; determination of spinal column stability including

computer models of primate spinal column; post-traumatic alteration in blood-spinal cord barrier; the effect of biogenic amines on the resulting neurological dysfunction and ultrastructural analysis of the effect of impact trauma; the development and study of a model system in the Larvil Lamprey (Petromyzon Marinus) for study of regeneration in the central nervous system; a study of the formation of peripheral neuroma and the factors controlling its size; and, study of the olfactory bulb re-establishment of central synaptic connection post-injury.

Program of Research in Spinal Cord Injury

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Sponsor: National Institutes of Health

Purpose — This program is concerned with multidisciplinary studies of the consequences of experimental spinal cord injury. Four of the five projects involve physiological, biochemical, and pharmacological studies of descending locomotor control mechanisms in cats and monkeys. The fifth is a study of the process of axonal myelin disintegration after blunt trauma to the spinal cord, with special interest in endogenous degradative enzymes.

Fundamental Studies in Spinal Cord Injury

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Sponsor: National Institutes of Health

Purpose — The primary objectives of this proposal are to: 1) correlate alterations in the somatosensory evoked potential (SEP) with specific spinal cord lesions; 2) study the electrophysiological alterations occurring in the SEP following graded trauma; 3) study the effects of trauma and the influence of other agents on the isolated *in vitro* spinal cord; and 4) develop and test methods of computer analysis for the rapid recognition, differentiation, and characterization of SEP's.

Progress — Methods used entail the following: 1) measurements of amplitude, latency configuration, and Euclidean distance; 2) the use of a standard weight drop apparatus to produce trauma; 3) the use of the recorded far-field potential to determine its effectiveness as a reliable measure of spinal cord trauma; 4) use of an *in vitro* spinal cord model to separate effects of mechanical trauma from ischemia-induced necrosis resulting from impaired microcirculation; 5) development of a reliable model to mimic spinal cord trauma; and 6) continued development and application of computer analysis for SEP classification.

A Feasibility Study on Detection of Impending Pressure Sores Using Ultrasound

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objectives of this study are to develop ultrasonic techniques to assess the state of superficial and deep tissues with respect to early changes that signal the incipient development of tissue breakdown as well as changes during the healing process.

Progress — This study has approached the problem by means of an experimental model in pigs. Tissue damage in pigs is created by applying a constant force

through specially shaped indentors under the control of a microprocessor. This model is employed to create a known degree of tissue damage on which specific acoustic parameters can be measured for comparison to normal. Acoustic parameters, namely, attenuation and integrated backscatter, will be measured over normal and pressure damaged tissue or regions utilizing an ultrasonic pulse echo system. An IBM instrumentation computer is used for acquiring and processing ultrasonic data. Reflected ultrasonic data are sampled at 50 mHz using a Biomation 8100 A/D converter. Correlation of acoustic parameters with histology of pressure damaged tissues is laying the groundwork for future development of a routine noninvasive, clinical ultrasonic test that could warn of impending pressure sores and whether the changes were occurring in deep or superficial tissues.

Clinical problems associated with the effects of mechanical pressure on soft tissue represent one of the great challenges in the management of handicapped individuals. Due to the high cost of care and management of patients with pressure sores, it is important to gain further understanding of their etiology, and to develop techniques that permit early prediction or detection of impending tissue breakdown in time to take corrective action. Prediction of risk from pressure sores is based on measurement of external factors (such as interface pressure), but predictions are unreliable within tissue. Furthermore, external measurements do not monitor the actual state of the tissues, yet patients react differently to similar environmental conditions. Detection of incipient pressure sores implies some direct means of measuring the actual condition of the tissues. This study is investigating the feasibility of utilizing ultrasonic techniques for this purpose with special reference to deep tissues.

The Biofeedback Incontinence Training Program

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Sponsor: VA Rehabilitation Research and Development Service, Olin E. Teague Veterans Center

Purpose — The principle of biofeedback is defined as the use of electronic equipment to reveal specified physiological events to the individual. Control of otherwise involuntary events is learned by manipulation of the electronic feedback signals. In this case, electromyography (EMG) is used to monitor muscle activity at the rectal sphincter. The urinary and external anal sphincters are by design two halves of a figure eight of muscle tissue. By collecting data on the contractile activity of the more superficial muscle at the anus, correlated activity of the bladder sphincter is known. With this tool for physiological awareness, the subject can exercise selectively the target/problem muscles. Increased muscle tone and control of sphincter function aids in the control of urine flow/leaking.

Progress — Approximately 25 individuals were referred to the investigator as having urinary incontinence. Of these, ten met the overall criteria for the study and completed the treatment program. The participants' ages ranged from 57-78 (M = 67) and were ambulatory and self-care. Some of the subjects managed the leaking urine with pads; others utilized external urine collecting devices.

Subjects were interviewed by the investigator to determine if each met the criteria of the study and to obtain a health history regarding incontinence. Selected subjects were asked to maintain a two-week record of bladder leaking

urgency for baseline information. Biofeedback treatment sessions were scheduled at two-week intervals and consisted of review of the current bladder record and practice of sphincter exercises while attached to the EMG recorder. Subjects were instructed to perform the simple exercises on a daily basis.

Preliminary Results — Ten subjects completed the B-FIT Program (urgency n=3, stress n=2, p-surgical n=5). The subjects with urgency were able to decrease the frequency of urges to within normal limits and thereby control leaking episodes. The stress incontinent subjects were able to decrease leaking by 66 percent and 88 percent. The three post-surgical subjects were able to decrease leaking by 75 percent, 75 percent and 79 percent, respectively. The two post-surgical subjects had been incontinent for more than 20 years and did not respond to the intervention.

The results of this study reinforce the importance of assessment of bladder and bowel habits to determine the type of urinary incontinence to be treated.

Residual Bladder Volume Determination for Spinal Cord Injury Patients

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Sponsor: VA Rehabilitaton Research and Development Service

Progress — During the past year we have: 1) completed our laboratory testing with our prototype system; and 2) used those results to modify and simplify our data sampling process and to develop a post-processing algorithm for improved accuracy. The simpler, improved approach has given an average accuracy of better than eight percent with a standard deviation of five percent for 15 subjects with volumes between 50 and 300 cc. Further post-processing improvements are now being incorporated. The final design of all components for the clinical prototype system have been completed, all individual components have been checked, and the prototype system is being put together for interface checks and clinical tests in Fall 1986.

The Spasticity of Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This research utilizes electrophysiologic testing of spinal reflexes to examine the neurophysiologic changes which accompany the appearance of spasticity following spinal cord injury (SCI). The objectives are: 1) to describe the temporal course of reflex changes both for stretch reflex and withdrawal reflex pathways after SCI; and 2) to correlate electrophysiologic measures of spinal reflex activity with clinical assessments of hyperreflexia.

Progress — Electrically-elicited Hoffman (H) and mechanically-elicited tendon (T) reflexes, electrically-elicited withdrawal reflexes and direct muscle (M) responses are recorded serially through one year following acute spinal cord injury. Cauda equina afferent and efferent potentials that accompany the H and T reflexes also are recorded. Measures of reflex excitability include H/M and T/M amplitude ratios for the muscle potentials and efferent/afferent ratios for the cauda equina potentials.

Methodologic observations in control subjects reveal that placement of recording electrodes overlying the calf muscles markedly influences the H/M ratio and that placement well above or below the gastrocnemius-soleus junction minimizes excessive serial variation due to technique. In acute SCI patients, a characteristic time-course of H reflex changes is seen with H/M ratios increasing transiently between one and four weeks and again between two and five months. This latter increase in H/M ratio is due to an increase in H reflex amplitude rather than a decrease in M response amplitude. Yet to be addressed in this research is the assessment of stretch reflex excitability by using cauda equina potentials and the temporal course of withdrawal reflex changes.

Evaluation and Rehabilitation of Reproductive Function in Paraplegia

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Sponsor: VA Rehabilitation Research and Development Service

Progress — Efforts have been directed over a period of nine years to develop methods and equipment for assessment of the reproductive potential of male paraplegics. Rectal probe electrostimulation equipment has permitted the delivery of appropriate electric current, with complete electrical safety, to elicit erection and seminal emission. The problem of retrograde seminal fluid flow into the bladder has been investigated via studies involving various catheter designs and balloon inflation pressures to block the bladder neck. Testicular biopsies, profiling of serum reproductive hormones, and semen evaluation (of sperm motility and morphology) also have added to our knowledge of the overall reproductive status of these patients.

We have carried out 79 studies on 38 spinal cord injury patients. Intolerance to adequate current delivery for erection and seminal emission was common among patients with cauda equina lesions. Seminal emissions were obtained from 58 studies in 73 percent in these 38 patients. Total sperm count was variable; in 42 studies (79 percent), it was greater than 20 million. Sperm progressive motility usually was low; in 83 percent of the 58 emissions, it was less than 20 percent. Efforts are being directed to study and improve sperm motility of seminal emissions in order to fulfill the ultimate goal of this project, which is the effective use of collected sperm from paraplegic males in insemination for siring normal children.

Devices for Female Urine Incontinence

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Urinary incontinence, both a medical challenge and a social embarrassment, afflicts five to ten million Americans. An external urine collection device for women, comparable to the condom-type catheter for men, is not commercially available. Currently available noninvasive products for management of urinary incontinence in women are inconvenient, their use is associated with socially unacceptable odors, and they are confining and frequently ineffective. The customary method for management of urinary incontinence in women, the indwelling catheter, invariably leads to bacteriuria which may be the

most common nosocomial infection in this country. As a viable alternative to the indwelling catheter, an external urine collection device for women must be effective in managing urinary incontinence, have a high degree of patient acceptance and have the potential to decrease the incidence of bacteriuria and its sequelae. Such a device would likely reduce health care costs and prevent otherwise unnecessary institutional admissions.

Progress — The Infectious Diseases Research Laboratory at the Baltimore VA Medical Center is conducting clinical evaluations in women to determine efficacy of prototype external urinary incontinence devices. Initial clinical studies in non-ambulatory women have evaluated device efficacy for five consecutive days of wear time. Results from these short-term clinical trials indicate that prototypes are easy to apply, are effective in managing urinary incontinence [average wear time of 29 hours while containing an average urinary output of 1,500 cc without leakage], and have excellent patient acceptance. Adverse reactions have not occurred. Continued evaluation, using design modifications suggested from results of initial studies, will focus on efficacy of devices for extended wear times and in ambulatory patients.

Spinal Cord Explants Cultured on Carbon Filaments and Stimulated with Direct Current

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Sponsor: Paralyzed Veterans of America, Vaughan Chapter

Purpose — Following complete spinal cord transection in mammals, nerve fibers above the transection begin to regrow, but, this growth is usually transient. It has been thought that the environment at the site of the injury was unfavorable to growing and regenerating axons. Many investigators have attempted to modify the microenvironment to make it more favorable to nerve fiber regrowth. One of these ways has been to stimulate regrowth with minute electric currents. But, the process of axonal regeneration alone is not sufficient for functional recovery. The growing axons must be guided and directed to their proper destination.

A few laboratories have reported successful implants of carbon filaments as substitutes for injured ligaments and tendons, in both experimental and clinical studies. Carbon filaments provide mechanical strength and act as a scaffold for the development of new aligned fibrous tissue. The filaments eventually degrade as the new tissue matures.

Progress — This study was designed to evaluate the influence of carbon filaments on the growth and orientation of nerve fibers from spinal cord explants *in vitro*. For this study we designed a petri dish in which we attached approximately 3000 carbon filaments (8 to 10 μm diameter) to the bottom of the dish with their free ends extending through and beyond the dish. We then sterilized the entire assembly. We placed spinal cord explants on the carbon filaments, with the free ends of the filaments attached to a 0.2 μamp direct current source.

We prepared spinal cord explants consisting of one to two millimeters thick thoracolumbar cord segments from 15- to 17-day-old rat embryos under sterile conditions. All explants were grown for three weeks in Dulbecco's modification

of Eagles medium supplemented with fetal calf serum, glucose, and penicillin-streptomycin at 37 degrees Centigrade in a humidified 95 percent air and five percent CO_2 atmosphere. At the end of three weeks we rinsed all culture dishes with physiological saline. Using an ocular micrometer, we measured fibrous outgrowth from the edge of the explant to its most distal point.

We observed healthy explants after three weeks in culture. A scanning electron microscope (SEM) showed us that outgrowth from explants was parallel to the longitudinal axis of the carbon filaments. Neurites from the explants were growing on and in between the carbon filaments. The outgrowth we observed with SEM appeared to be both nerve fibers (when stained with silver protargol method) and glial fibers (when stained with immunoperoxidase method). In electrically stimulated explants, neurite length was greater towards the negative pole.

We believe that the carbon filaments provide support and guidance for the growing fibers from the spinal cord explants in tissue culture. A 0.2 μamp constant current passed through the carbon filaments enhancing fiber growth.

Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project's goal is to learn more about the underlying mechanisms of bladder dysfunction following spinal trauma and to use this knowledge to develop ways to enhance the recovery of bladder function after spinal trauma. It compliments our other studies, which focus on ways to overcome paralysis in humans.

Progress — We have two objectives for this project: 1) develop an animal model to study micturition dysfunction after spinal trauma, and 2) use this model to study the effects of various drugs on the spinal control of micturition. We chronically measure the relationship between bladder volume and pressure before and after the spinal administration of opiate agonists and antagonists, and before and after spinal trauma, using pairs of ultrasonic crystals that have been implanted in the bladder wall and a miniature pressure transducer implanted into the bladder.

Our research should lead to a better understanding of the neurophysiology and neuropharmacology of bladder function because we can measure and manipulate many of the neural and muscular events underlying bladder function in the unanesthetized animal. Such understanding is needed because renal complications remain the number one cause of death during the long-term management of the spinal cord injured patient. These complications are a direct result of the bladder dysfunction that almost always accompanies spinal cord injury.

C. Spinal Cord Regeneration

Axon Regeneration in the Mammalian Spinal Cord in Response to Surgical Denervation and Nerve Growth Factor

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — The objective of this project is to perform dorsal rhizotomies to quantitate sprouting of axons in Lissauer's tract and in the dorsal columns.

Progress — In order to assess sprouting of intrinsic nerve processes in Lissauer's tract, the sensory axons were surgically removed unilaterally by a series of dorsal rhizotomies. To do this, 200 to 250 gram male and female rats were anesthetized by an intraperitoneal injection of sodium pentobarbital (40 mg/kg). A unilateral laminectomy was done either on the left or the right side, the dura and arachnoid membranes opened and dorsal roots of thoracic segments T4 through T9 were identified and cut. A combination of frequent H_2O_2 (three percent solution) application and gel foam was used to minimize bleeding.

Following surgery, a strip of Dow corning Silastic sheeting (subdural implant material) was placed on top of the exposed spinal cord and roots, the musculature was sutured and the skin incision was closed by autoclips. After this procedure, the rats were usually eating and drinking within one hour. The rats are surviving well and will be allowed survival time of one month, three months, and one year at which time the dorsal rhizotomies described above will be repeated acutely.

To assess sprouting in the dorsal columns, the surgical procedures were as described above but the chronic and acute dorsal rhizotomies were performed for segments L1-L6, S1-S4 and C1-C3. These surgeries are still in progress.

Trophic Interactions Between Nerve Terminals and Their Target Tissues

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Purpose — The focus of this research is to study the trophic influences exerted by normal nerves upon the cell population of their target tissues, and the changes that occur after damage to the nerve. The mammalian taste bud and its gustatory nerve supply is being used as a model tissue for these studies.

The taste bud exists as a collection of elongated cells situated amidst the epithelial cells of the tongue. The dependence of the taste bud cell population upon its gustatory nerve supply is extraordinary. Serving the gustatory nerve supply is extraordinary: severing the gustatory nerve results in degeneration of the taste bud cells and disappearance of the taste bud. When the nerve regenerates (nerves outside the spinal cord have this ability), the taste buds are reconstituted from the epithelial cell. This is in contrast to the case of a muscle after damage to its motor nerve, where the muscle cells do not regenerate upon regeneration of the nerve. Furthermore, the taste bud cells normally have a relatively brief lifespan. The cell population of the taste bud is constantly being renewed by differentiation and migration of cells from the surrounding epithelia, and this turnover of cells

also is thought to be under the direct influence of the gustatory nerve. Thus, the taste bud cell population and its gustatory nerve supply represents a powerful model for studying neuronal trophic mechanisms that are important for maintaining the integrity of a target when its nerve supply is intact, and for rejuvenating a target when its nerve supply is restored after damage.

The data collected in these studies will represent the first precise quantitative analysis of trophic regulation on a target cell's turnover rate by its nerve supply, and thereby provide new information essential to future studies on the identification of the factor(s) responsible for this control of growth.

Progress — Results from the project to date have been encouraging. The point at which new cells enter the taste bud has been described, as well as their later movement as they mature and eventually are lost. The nature of the maturation process itself, which can be likened to a shortened process of development and aging, also is beginning to unfold. These initial studies on animals with an intact nerve supply are progressing well, and the outlook is good that planned denervation experiments (severing or crushing the gustatory nerve) will be undertaken soon. These experiments will provide enlightening. Indeed, comparison of the results from intact animals with those from denervated animals will be tantamount to an understanding of the manner in which nerves and their targets interact to maintain a viable, functioning system.

Studies of CNS Regeneration: Changes in the Astrocyte Cell Surface Membrane Following CNS Injuries and During Development

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — When axons in the adult mammalian Central Nervous System (CNS) are injured, they undergo regenerative sprouting, but these sprouts fail to grow for more than a few millimeters. The inability of injured CNS axons to grow for long distances in order to reach their appropriate target cells may be largely responsible for the many functional deficits seen following injuries to the adult mammalian brain and spinal cord. On the other hand, when peripheral nerve axons are injured, they can successfully regenerate for considerable distances. This capacity for axonal regrowth in the Peripheral Nervous System (PNS) is believed to be due in part to the longitudinally arranged columns of Schwann cells (non-neuronal cells).

Recent transplantation studies have demonstrated that CNS neurons located in many different areas of the adult mammalian brain and spinal cord are capable of extensive axonal growth through peripheral nerve grafts. These and other studies suggest that the differences in the regenerative responses in the injured PNS and CNS may be more dependent upon the non-neuronal glial environment surrounding the injured axons than upon the neurons alone.

The nervous system may be divided into neuronal and glial compartments. The glial compartment in the CNS consists of three types of cells—astrocytes, oligodendrocytes, and microglia. Of these glial cell types, the astrocytes may play a crucial role in the response of the CNS to injuries.

Neuron-glial interactions also are believed to be important for many develop-

mental events. In contrast to the extensive axon growth that occurs normally in the CNS during development, axon growth is minimal in the injured adult CNS. These differences may be due to glial changes that occur during development or in response to CNS injuries. Such changes might be expected to occur in the cell surface membranes, which are sites where neuron and glial cells interact.

The investigator proposes to study the changes that might occur in the cell surface membranes following CNS injuries and during development. This will be accomplished by generating momoclos antibodies to various components of the cell surface membranes. These antibodies will then serve as markers to identify which molecules change in response to CNS injuries and whether such molecules play any role in the regeneration of axons.

Axonal Regeneration in the Adult Spinal Cord

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Purpose — Spinal dorsal root axons return sensory information from skin, muscle, the descending colon and rectum, the sex organs, and the urinary bladder back to the spinal cord and the brain where sensations are consciously perceived. More importantly, this sensory information is essential to the reflex functioning of these organs. To spinal cord injury patients this information is particularly important as they depend on these visceral reflexes to carry out bodily functions.

Researchers have looked at the problem of dorsal root regeneration in mammals and for years their studies report that the dorsal root axons do not reenter the spinal cord due to barriers formed by the glial cells, the supporting cells of the central nervous system. Recently, however, a technique using an axonal tracer, horseradish peroxidase (HRP), which labels regenerating axons, has shown that cut or crushed dorsal root axons in adult frogs regenerate into the spinal cord where they are able to grow and reestablish connections. Previous studies found that some axons can actually regenerate into the spinal cord of cats and make functional connections if they are routed through a dorsal root. This observation has been confirmed and extended by using the axonal tracer HRP.

These studies are particularly important because they suggest that the glial barrier, which has been reported to prevent dorsal root axons from reentering the cord, is not an impenetrable barrier to all axons. Moreover, they show that once axons have penetrated the central nervous system, their growth is supported by the environment of the adult mammalian spinal cord.

Progress — For the past two years HRP has been used to study the regeneration of different types of axons into and within the adult frog spinal cord. The work indicates that some regions of the adult frog spinal cord differ with respect to their ability to support axonal growth. Electron microscopy shows that regions of the adult frog spinal cord that more closely resemble the embryonic or developing spinal cord appear to be more supportive of axonal regeneration.

Although work to this point has used the frog as a model for axonal regeneration, work is now extended to a study of regenerating dorsal root axons in adult rats using HRP where greater sensitivity of the HRP reveals a small number of regenerating axons missed with previous techniques. Different types of glial

cells in the spinal cords of frogs and rats also will be studied. By using antibodies that specifically label different types of glial cell, those of the frog and the rat will be compared and types that respond to dorsal root injury in the two species will be identified. This may explain why a greater number of dorsal axons regenerate in the frog.

It is hoped that this research will lead to other studies directed at ways to increase the chances of individual axons entering and growing within the spinal cord.

Protein Transport in Injured CNS Axons

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Purpose — Corticospinal axons, those fibers connecting the motor cortex region of the brain to the output neurons in the spinal cord, control the voluntary movements of the body. When they are injured motor ability is lost since, unlike axons in peripheral nerves which can regrow from the point of injury, corticospinal axons cannot regenerate. The Golden hamster is an ideal model for studies in determining differences in ability of corticospinal axons to regenerate since they can regenerate these axons in the first two weeks of life but not at later ages.

The researcher previously looked at the properties of the corticospinal neurons during the time regeneration is possible and during the periods when it is not to determine the major changes in the cell. Particularly, the studies concentrated on the process of delivery of proteins, known as slow axonal transport, which is directly related to axonal regrowth since it delivers the proteins needed to build a new axon. Transport was compared in normal adult and immature corticospinal axons and it was found that the rates of transport differed between immature and mature axons and that several proteins were absent or present in smaller amounts in the immature axons.

Progress — The researcher hopes to study the changes in protein synthesis and slow axonal transport after an axonal injury, using the previous studies as a baseline in order to identify the signal sent to the cell body after injury. This causes the cell to alter its metabolism making regeneration no longer possible. Some studies indicate that cells capable of regenerating increase the production of certain proteins essential for the reconstruction of an axon and decrease their production of unnecessary proteins.

Adult and immature Golden hamsters will have the spinal cord on one side of the body surgically severed. The hypothesis is: if protein synthesis changes, this will be detected when small amounts of radioactive amino acids are injected into the motor cortex region of the brain (where the nerve cell bodies give rise to the corticospinal axons). The corticospinal neurons will take up the labeled precusor (the amino acids) and use them in synthesizing proteins, which will then be transported into the intact regions of the axons. There the rate and mechanism of transport can be studied as well as any alterations in proteins which were synthesized and transported in injured corticospinal axons.

The researcher hopes to define on a molecular level, for the first time, that the injury response of mammalian CNS neurons during a transition from a stage at regrowth is possible to an adult, incompetent stage. By defining a biochemical response, future attempts to modify the response using pharmacological or genetic tools is possible.

Central Nervous System Regeneration in Nerve Grafts

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Purpose — The objective of the research was to determine some of the factors that govern successful sprouting and elongation of central nervous system (CNS) neurons into peripheral nerve grafts which were inserted into the CNS of an adult rat. Determination of these factors may allow the development of techniques to enhance regrowth of CNS neurons.

Progress — The basic experimental design involved examining the response of CNS axons following their transection under three different conditions. The axons were labeled with wheat germ agglutinin linked to horseradish peroxidase (WGA-HRP) and studied under light microscopy. The distance an axon dies back from where it was cut was called axonal retraction, which appears to be related to the amount of damage an axon sustains after injury. Less severely damaged axons may be more likely to regenerate. The appearance of damaged axons' endings also may indicate their ability to regenerate.

The degree of axonal retraction and the percentage of each type of axonal endings were studied when three conditions were varied: control versus implanted graft; the distance between the injury and the cell body; and time. The control versus implanted graft condition was designed to determine how the presence of a nerve graft alters an axon's response to injury in order to promote axonal regeneration. Varying the distance between the injury site and the neuron's cell body examined whether the axonal response to injury of nearby and distant neurons was correlated to the different probabilities by which nearby and distant neurons enter a nerve graft. The time course of axonal sprouting and entry into the nerve graft was examined to compare it to that seen in peripheral nerves where regeneration is rapid and successful.

1) Axonal Retraction Distance: most axonal endings were found quite close to the lesion site with a smaller number scattered at greater retraction distances. Up to the sixth day following the lesion, no axon was observed to penetrate a nerve graft or to cross the original lesion site.

a) When control and nerve grafted animals were compared under the same distance and time conditions, the amount of retraction was always greater on the control side. Therefore, the graft seems to exert a protective influence on the axonal ending.

b) A small but significant difference in the same direction was observed in graft-implanted rats at six days.

c) There was a clear difference in the time course of axonal retraction between 3 mm and 6 mm lesioned rats. It appears that the more distally transected axons are still retracting while the nearby transected axons have already begun to advance at six days.

2) Ending Types: analysis of the distribution of ending types as characterized by morphological structure under various treatments was undertaken to determine the changes in the proportions of ending types that normally occur with time and to examine what effect the nerve graft has on the distribution. (The types were ball, balloon, beaded, club, lance, and sprout. In all conditions the major ending type was the ball ending. Of particular interest was the distribution of sprouting endings since such endings are often taken as the initial sign of the initiation of regeneration).

a) At day one, the distribution of ending types was similar for both control and graft cases with ball endings predominating and club endings numerous. At six days, the proportion of ball endings increased but sprouting endings decreased. Thus, the graft does not seem to promote axonal elongation by increasing the proportion of sprouting axons.

b) Based on comparison of 3 mm and 6 mm lesions, the graft does not differentiate between nearby and distant neurons on the basis of promoting differential sprouting. Definite changes in type distribution occur in time with the proportion of sprouts rising dramatically (3 to 5 times) between day one and three and may start as early as three days.

3) Loss of Axonal Endings: a major observation is the dramatic decrease (50 percent) in the number of labeled endings between days one and six. A 50 percent decrease in the number of labeled axons is quite consistent with observations of cell death following axonal section.

4) Axonal Diameter: two of our observations confirmed that larger diameter axons show greater retraction following injury than small diameter axons. Also, at six days, most of the remaining axons appeared to be of a smaller diameter.

Preliminary Results — 1) Intrinsic control of CNS neurons to axonal lesions at different distances is in the appropriate direction to explain the observed differences in axonal regrowth. 2) The nerve graft produced two clear effects—it retards the normal amount of axonal retraction following injury, and the graft alters the proportions of ending types in comparison to controls in as little as six days.

The ways in which the graft does not increase regenerative responses are also instructive. The graft does not increase growth by reducing apparent cell death nor does it appear to increase the regenerative potential of CNS neurons by shortening the initiation time or by increasing the frequency of obvious sprouting.

Functional Spinal Cord Regeneration (Cats)

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Sponsor: National Institutes of Health

Purpose — Our laboratory is devoted to the study of functional regeneration in the mammalian spinal cord. The model system under study is the spinal cord of the adult cat. Specifically, this project investigates the possibility that spindle group II afferents may generate new functional connections with spinal motoneurons. Synaptic sites are made available on these motoneurons as a consequence of temporary ischemia of the spinal cord, eliminating interneurons normally occupying about 95 percent of all synaptic sites on motoneurons.

The fundamental question asked is whether spindle group II afferents sprout to form new functional contacts in response to the presence of newly available synaptic sites in the post-ischemic spinal cord. The existence of new group II-motoneuron synapses would be suggested by the presence of single fiber spindle group II EPSPs of unusually large magnitude (greater than 100 uV) or in an unusually large number of motoneurons (the percentage will depend upon the conduction velocity of the particular afferent). In addition, a number of other important questions will be asked concerning neuronal function in the post-traumatic cord: are single fiber EPSPs then different in configuration (indicative) of altered synaptic location on the soma-dendritic membrance)? Are different types of motoneurons contacted? Are denervated motoneurons more or less excitable (rheobase, repetitive firing properties)?

Recovery and Regeneration After Spinal Neuron Injury

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Sponsor: National Institutes of Health

Purpose — The program project supports an interdisciplinary series of projects on the mechanisms underlying the effects produced by severing afferent or efferent connections to or from neurons of regeneration sprouting and/or reinnervation. The purposes of the programmatic approach are: 1) to stimulate interaction and collaboration by investigators from four departments of three institutions; and 2) to support shared facilities at the University of North Carolina.

The seven projects are directed at: a) the relation of behavioral recovery to the regeneration of long-descending tracts after spinal cord section; b) possible synaptic reorganization in ascending sensory systems after spinal chordotomy; c) central consequences (neuronal degeneration and death) after peripheral sensory fiber injury; d) the sensory and efferent consequences of chronic renal denervation and reinnervation; e) the modifications in effector organ (skeletal muscle and kidney) or sense organ behavior following spinal nerve injury and regeneration; and f) biochemical changes in spinal motoneurons following injury and regeneration.

Muscle Reinnervation and Neurotrophic Influence (Anurans, Rodents)

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Sponsor: National Institutes of Health

Purpose — The physiological properties of the spinal cord and its regenerative capacity will be studied in mammals rendered paraplegic by transecting the spinal cord at T5 or by injecting 6-aminonicotinamide, batrachotoxin, or tetrodotoxin into the subarachnoid space. Spinal reflexes, neuromuscular transmission, and membrane properties of slow and fast muscles will be measured to determine: 1) the effect of drugs and toxins that inhibit gliosis; 2) the effect of hibernation (in which glial and connective tissue scarring is suppressed); 3) the effect of toxins which alter the ionic composition of the extracellular space surrounding the neurons; and 4) the effect of the hibernating (sleep) factor on the physiological and regenerative properties of the neuromuscular systems of nonhibernating mammals.

The relation of axonal transport to the maintenance of the membrane properties of slow and fast muscles will be examined.

The interaction between the dystrophic gene and neurotrophic influences will be examined in dystrophic chicken muscle during denervation, reinnervation, and hyperinnervation. The effect of pumiliotoxin (which we have found to suppress the symptomatology of the disease) will be studied.

Drugs and toxins such as amantadine, naloxone, quinacrine, atropine, piperocaine, batrachotoxin, gephyrotoxin, pumiliotoxin, and histrionicotoxin will be used to probe the function of the ACh receptor-ionic channel complex.

Progress — Isolation and purification of the ACh receptor and ionic channel proteins have been sufficiently accomplished in our laboratory to enable us to attempt to reconstitute these macromolecules in artificial lipid membranes. Ionic permeability of these functional, ion-conducting membranes will be assessed as well as the effects of receptor and channel-blocking drugs such as those named.

D. Independent Living for the Severely Disabled

Promoting Consumer Involvement

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Sponsor: National Institute of Handicapped Research

Purpose — Teaching consumers with severe disabilities new ways to improve their community and its services is a promising approach to promote independent living. In the past three years, the investigators have developed and evaluated the Concerns Report Method. This unique self-help method allows disabled citizens and their families to assess, prioritize, and convey their concerns to decision makers.

Progress — To date, nearly 2,000 disabled residents have used the Concerns Report Method to establish priorities for independent living services. These include over 500 persons with disabilities in nine different local applications in Kansas and Missouri. Another 1,400 Kansas residents with severe disabilities participated in a related project that set a statewide action agenda. Approximately 4,000 additional disabled citizens were identified as participants in current applications in Washington, D.C. and Los Angeles.

Preliminary Results — This information helps organizations and decision makers identify concerns and consider potential solutions from the perspective of consumers. State, regional, and national data will be combined to provide a profile of the concerns of disabled consumers. These reports can be used by elected officials and service providers to better utilize existing resources to meet the needs of their constituents.

Future Plans — We plan to expand use of the Concerns Report Method with new projects throughout the country. Additional applications are planned for Des Moines, IA; Columbia, MO; Wichita, KS; Norfolk, NE; Salt Lake City, UT; and Missoula and Helena, MT. The Method will be used to establish service priorities in these or other sites as requests for this unique planning tool are met.

Involving Disabled Consumers in Community Change

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Purpose — Many community decisions affect individuals with disabilities and their families. For disabled persons to achieve equal opportunities they must assume leadership roles in their community. Research on consumer leadership and advocacy is designed to help consumers organize into small groups to monitor ILC operation and community affairs.

Progress — Project staff have prepared self-help guides on how to identify, select, report, and discuss issues; lead group discussions; and take action on issues. Procedures for establishing effective consumer groups and training current and new members also have been prepared, evaluated, and disseminated to interested consumer groups.

To effectively take action on an issue requires that the group understand the range of potentially successful actions that can be taken. A hierarchy of 25 possible actions, appropriate for use by consumer organizations, has been identified. These actions allow consumer groups to make recommendations and participate in decisions about issues affecting them.

Future Plans — Field tests of these procedures have already contributed to a number of changes in local ILC programs and city policies. Project staff plan to implement and evaluate the consumer involvement model with six additional consumer groups during the next 18 months.

Training Attendant Care Management Skills

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Sponsor: National Institute of Handicapped Research

Purpose — Attendant care is a vital service for many people with disabilities who live independently. Until now, there has been no empirically-based model for teaching consumers how to train and manage an attendant.

The investigators have adapted management techniques that have been successful in other settings for use in attendant care. These techniques address two common management problems—lack of job specificaton for attendants and inability to provide objective, corrective feedback on attendant's work performance.

Progress — Performance checklists are used to provide instructions to caregivers in how to conduct routines. They also allow consumers to monitor, evaluate, and

provide feedback to caregivers on their performance. Once training is complete the checklists are used to maintain consistent performance.

The training and management procedures have been field-tested with consumers and a training manual for consumers has been completed. Project staff are now working on complementary materials to train ILC staff to implement the consumer training program in their own setting. Plans for the next year include field-testing the complete procedures package in two settings.

Encouraging Dignified Service Provision

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Sponsor: National Institute of Handicapped Research

Purpose — People with disabilities frequently must deal with human service agencies, such as local welfare offices, that can be insensitive to their needs. From applications of the Concerns Report Method, we have identified a perceived lack of courtesy in service provision as a major concern of people with disabilities.

Progress — The investigators have outlined a research study to address this issue. The study entails developing an assessment protocol for consumer groups to monitor the degree to which human service agency personnel treat them with dignity. Consumers are then provided with strategies for encouraging more dignified treatment, when appropriate. Working with local consumer groups, the investigators will specify the behaviors involved in providing dignified treatment. Improving courtesy and respect shown to disabled consumers should increase satisfaction with human services, and this will, in turn, support efforts by persons with disabilities to live independently.

Promoting Community Support for Independent Living

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Sponsor: National Institute of Handicapped Research

Purpose — A top concern for independent living technology development is how to enlist community support for issues related to independent living. Most ILCs agree it is essential to gain community support and their current efforts could be more successful.

Progress — The investigators have initiated a research program to identify, develop, validate, and disseminate procedures to promote community support for independent living. Based on information provided by ILCs, information packages designed to educate the public and promote community support will be prepared. For example, a model slide presentation on the services provided by a local ILC might be prepared. It would include an overview of the program's philosophy, a description of the agency's consumers and staff, and information about each service provided by the agency. Similarly, model information packages might be prepared for radio and television public service announcements, brochures describing the center's services, and newspaper press releases.

Each model information package will be based on a task analysis designed to identify the critical components of the package. The task analysis will be based on interviews with successful programs and a review of the literature. The task analysis phase will produce a tentative sequence of responses designed to communicate information effectively.

Finally, self-help guides will be prepared to allow ILCs to adapt model information packages for their own use. For example, a written guide on adapting the model slide presentation might include chapters on how to edit a presentation script to describe local services and concerns, how to develop the slide program, how to deliver a scripted slide presentation, how to evaluate the impact of the presentation on an audience.

Each self-help guide will be pilot-tested under analog conditions to determine its effects on teaching people how to adapt model informational packages. This evaluation will provide an opportunity to modify and revise procedures before they are disseminated to ILCs.

Improving Media Portrayals of Persons with Disabilities

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Sponsor: National Institute of Handicapped Research

Purpose — Media professionals are in an ideal position to shape the public image of people with disabilities. Their capacity to communicate ideas and present appropriate models is unequaled in our society. Yet, the media have been criticized for perpetuating stereotypes through inaccurate portrayals of disabled people.

Inaccurate portrayals may persist because of no clear guidelines indicating preferred style and terminology for writing and reporting about disabilities. In response to recommendations from the RTC/IL Advisory Board and consumers nationwide, RTC/IL staff developed a pamphlet, "Guidelines for Reporting and Writing About People With Disabilities." It was compiled with input from over 50 national disability organizations and represents consensus opinion on acceptable terminology and portrayals concerning disability issues. Response has been phenomenal, and over 30,000 copies have been disseminated to disability organizations and service agencies throughout the country.

Progress — The Guidelines were submitted to the boards of editors of Associated Press and United Press International for possible inclusion in upcoming editions of their stylebooks. This would help establish national policies on use of disability terms and portrayals. But, in addition to national policies, consumer groups need strategies to influence portrayals by their own local media to help ensure adoption of an adherence to established guidelines. The investigators have initiated a program of research to develop and evaluate strategies to influence local media. Working with consumer groups in three cities, project staff will examine several strategies, including monitoring and providing feedback on the appropriateness of media features about disabled persons, and providing commendations and awards for exemplary media portrayals. The most effective intervention strategies will be packaged for dissemination to consumer groups in additional communities.

Evaluating the Impact of ILCs

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Sponsor: National Institute of Handicapped Research

Purpose — Independent living service providers and policymakers need valid, reliable, and economical methods to evaluate the impact of ILCs. The goal of the program evaluation project is to develop and field-test evaluation standards that can be used by ILCs. As a preliminary step, investigators have developed methods to measure attainment of consumer goals, ILC impact, and removal of handicapping conditions within the community.

Progress — In the next year, the validity and reliability of these measures will be examined, and protocols will be established for use of these measures to conduct internal and external evaluations of ILCs.

Extending Independent Living to New Populations

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Sponsor: National Institute of Handicapped Research

Purpose — ILCs may be instrumental in assisting mentally retarded persons with the transition to community living. However, ILCs have limited expertise in serving mentally retarded persons. This project will examine the feasibility of extending services to mentally retarded persons and determine problems and benefits associated with serving this population. A survey of ILCs will be conducted during the first year of the project in order to: 1) determine the extent to which ILCs provide—or are asked to provide—services to mentally retarded persons; 2) determine common problems in serving or reasons for not serving mentally retarded persons; and 3) identify ILCs that successfully serve mentally retarded persons and determine the reasons for their success.

Future Plans — Based on the results of this survey, future objectives for the project are to: 1) develop and evaluate training materials for ILC staff so they are better equipped to provide services to mentally retarded persons; and 2) develop or adapt IL services so they may be extended to include mentally retarded persons.

Social Support Systems for Enhancing Independent Living

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Sponsor: National Institute of Handicapped Research

Purpose — Self-help and social support have been major components of the IL movement. For many disabled citizens, ILCs are their primary social support system. Research analyzing social support systems is limited. Available literature primarily focuses on either theoretical discussions about the importance of social support or descriptions of individual support programs. There is little research demonstrating the effectiveness of such groups, in general, or their role in promoting independence of disabled persons, in particular. In the IL field, research is needed to determine: 1) the prevalence of social support systems for people with disabilities; 2) the relationship between social support groups and

ILCs; 3) characteristics of successful support systems; and 4) procedures needed to enhance social support group effectiveness.

Progress — The investigators plan a research project to gather this information. Survey information from ILCs throughout the country will be used to: 1) create a national directory on self-help social support groups for people with disabilities; 2) identify the characteristics, goals, and objectives of IL social support groups; 3) prepare a national directory of IL social support groups; and 4) identify functional variables that differentiate effective from less effective social support groups.

Future Plans — This information will be used in future years to develop training and technical assistance procedures for assisting ILCs in establishing effective social support groups.

RTC/IL plans a number of training and dissemination activities, in the areas of university training, inservice training and technical assistance, and product development and dissemination. University training will include courses in Human Development, Occupational Therapy, Community Psychology, Journalism, and Industrial and Interior Design. These courses provide an overview of the IL movement and the role of various professions in promoting independent living.

A full-time training associate will join RTC/IL staff next year. The training associate will conduct an annual survey of ILC technology needs, develop training and technical assistance activities to address these needs, and provide training and technical assistance to ILCs. Six regional inservice training workshops are planned. Additional, on-site technical assistance will be provided to ILCs as resources permit.

An IL leadership training program has been proposed wherein disabled persons will receive scholarships to pursue academic training and field-based practica. The program is intended to provide talented disabled persons with training and experience needed to assume leadership roles in the IL movement. Scholarships will be provided to three candidates next year, if resources permit.

Technology to Enhance Independence of Physically Disabled School Children

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Sponsor: Rehabilitation Engineering Department, Regency Park Centre for Young Disabled

Purpose — A recent study has shown the majority of children at the Regency Park Centre Special School experience problems with classroom skills, toiletting, and mealtime activities that could be overcome by the application of appropriate technology.

Our purpose is: 1) to investigate the needs established in our earlier study of classroom independence with a view to deciding whether the problems can be solved by commercially available technology or modifications to existing products, or whether a new design is needed; 2) to purchase those products that are available and to design, build, and provide new solutions where necessary; and 3) to measure the extent to which the disabled child's independence has been enhanced by the application of new technology.

Progress — In the preliminary phase the priority problem areas established in our earlier study will be investigated. Where problems have ready-made solutions, those solutions will be implemented. Design guidelines will be established for the new designs that need to be developed.

In the experimental phase designs will be fabricated and implemented with physically disabled children.

During the concluding phase follow-up measurements will be taken regarding the level of independence exhibited by children who have taken part in this project to determine the extent skill deficits have been compensated and independence has been enhanced by the application of technological solutions.

This project will have an industrial designer working with the existing staff of doctors, engineers, teachers, therapists, nurses, and assistants to design and implement solutions for the problems established that have high incidence and technological solutions. Devices will be developed to assist disabled school children with important areas of their lives, including classroom skills, toiletting, and mealtime activities.

The expected outcome is that the children will be made more independent with customized technological support so that some of them will be able to attend regular schools. The project will demonstrate how the introduction of technological innovations for physically disabled children in special schools and mainstream schools can improve the quality of their educational achievement.

Program in Social and Independent Living Skills

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Purpose — The objectives of this project are to develop and evaluate a comprehensive set of techniques to teach social and independent living skills to chronic mental patients. These techniques are intended to remediate the patient deficits that prevent them from attaining successful community adjustment and living up to their potential for a better quality of life.

A second major project goal is to develop the training technology to maximize its exportability to mental health and rehabilitation practitioners in a variety of clinical and applied settings. The training techniques are to be packaged with very specific instructional materials in the form of patient and therapist manuals and videotaped modeling stimuli to ensure that the materials for each skill content area, called a "module," will be used successfully. They are to be validated within the Social and Independent Living Skills (SILS) Program of the Rehabilitaton Medicine Service at the West Los Angeles VA Medical Center (Brentwood-Psychiatric Division).

Progress — Modules have been developed in several skill areas including conversation skills, leisure-recreational pursuits, grooming, problem-solving, cooking, money management, medication self-management, and homefinding. The modules are designed to have patients: 1) practice the skills that constitute the module within the treatment setting and in the community; and 2) learn structured methods of solving the problems that patients are likely to encounter when using the skills.

Each module consists of a major goal for community living (such as conversation skills, grooming, or recreational activities) and a series of approximately four to eight specific skills related to the attainment of that goal. The skills are taught using a combination of videotaped demonstrations, roleplay procedures, question/answer exercises, *in vivo* exercises, and homework assignments. Special attention is given to the areas of resource management and problem-solving obstacles to successful outcomes that are prerequisites to utilizing each skill and attaining module goals. Each patient participates in a three- to four-month day-treatment program that includes module training as well as case management, crisis intervention, and appropriate liaison with psychiatric and vocational rehabilitation services at the VA Medical Center.

Future Plans — Future research efforts will be directed toward evaluating, field-testing, and disseminating the modules that have been developed. Each module will be evaluated with respect to: 1) *skill attainment*, the degree to which patients are able to successfully demonstrate that they have acquired the requisite skills of the module; and 2) *treatment outcome*, the extent to which the requisite skills are maintained by the patient and generalized to the natural environment.

Rigorously diagnosed schizophrenic patients will be thoroughly evaluated before and immediately after completing the training program. Periodic follow-up measures also will be taken for 18 months. An interpersonal program of five skills areas considered to be critical for attaining successful community adjustment and improving the quality of life will be evaluated. Measures designed to assess improvement in interpersonal skills, problem-solving ability, and social adjustment will be made along with quality of life and psychopathology assessments. The modules will be field-tested at a variety of service settings throughout the United States prior to full scale dissemination.

E. Communication Methods and Systems for the Severely Disabled

MicroDEC II — Environmental Control System and Computer Access Aids

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Sponsor: National Institute of Handicapped Research

Purpose — The MicroDEC II system provides a person with limited motor ability, a common control medium through which electrical appliances, a telephone, and a personal computer can be operated. The system can be controlled remotely via a radio link that can be integrated with a digital wheelchair controller.

The device control features of the MicroDEC II are identical to those of the already commercially available MicroDEC Environmental Control System. The computer access features provide keyboard emulation for Apple II+ and IIe computers. Text creation, as for word processing, is enhanced through innovative

letter and word prediction schemes. In addition to pre-stored commonly used words, the MicroDEC II learns new words as they are spelled by the operator. These words are then incorporated into word prediction algorithm.

Progress — In the last progress report, it was indicated that the research phase of the MicroDEC II was completed and commercial development was being pursued. The MicroDEC II system is now being manufactured by Medical Equipment Distributors, Inc., of Maywood, Illinois, who also manufacture the original MicroDEC. We are presently assisting the manufacturer in the development of support materials.

PACA—Portable Anticipatory Communication Aid

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Purpose — The PACA is a one-year research and development project to design a portable computer communication aid that will enhance the communication abilities of non-vocal persons who also have physical impairments which preclude the use of direct selection techniques. The project has two primary objectives: 1) to augment the utility of traditional scanning communication aids by adding message element anticipation; and 2) to make this scanning communication aid cost effective to the user by capitalizing on the benefits of the innovative technology and competitive marketing of widely available commercial portable computers.

The PACA will incorporate features which address person-to-person (or conversational) communication, note taking, writing, and math calculations. Operation will be available in a single-switch automatic-scanning mode or a two-switch step-scanning mode.

Progress — The aid is being developed around a commercially available portable computer, the Epson HX-20. This computer has many intrinsic features that can be directly applied to the functional requirements of a communication aid, including battery operation, a multi-line dynamic display, a built-in printer and microcassette unit, input ports for switch operation, serial ports for accessory devices such as full-page printer or speech synthesizer, and is a small lightweight size. The HX-20 is also available at low initial cost (relative to dedicated electronic communication aids).

Because the majority of day-to-day communications are novel and cannot be properly effected through pre-stored messages, the focus of the PACA's message creation scheme has been on enhancing spelling and word selection. The Epson's LCD display is used for the presentation of dynamic selection arrays. Numerical linguistic analyses of American-English text are applied to rank message elements on the display according to conditional frequency of use. As selections are made, the aid attempts to anticipate subsequent selections and present those selections to the user in such a way as to increase the efficiency or the rate of message generation. Letters and words with greater probability of being selected are arranged in positions of the selection array that require fewer scanning steps.

In the letter selection mode, letters are arranged in a row-column format based on their probability of following the last selected letter. For word selection, core and learned word lists are accessed by first selecting the initital two letters. The core list is a permanently stored list of the 500 most frequently used American-English words from the million-word Brown University corpus. The learned list, which is initially empty, is filled by words not already in either list but which are added whenever the user spells a new word. Words in the learned list that are not used frequently are dropped in favor of newer words, in order to preserve topical relevance. For instances when pre-stored messages can be used effectively, or for maintaining personal memos, a scheme is provided for labeling, storing and retrieving messages, developed by letter and word selection.

The arrangement and partitioning of message elements and functions in the selection arrays, as well as the interaction between the anticipatory features and the user are being developed with the support of clinic and field trials.

Computer-Aided Motor Assessment and Rate Prediction for Prescription of Communication Devices

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Sponsor: National Institute of Neurological and Communicative Disorders and Stroke, Public Health Service, Department of Health and Human Services

Purpose — A means of determining a potential device user's expert rate as a prescription criterion is needed that will not require a lengthy practice period to measure it directly with each candidate.

Progress — The investigators have developed a system of computer-assisted assessment and calculation procedures which meets this need. It consists of two major components. The first is an objective assessment technique which taps the motor abilities relevant to use of most devices. It is conducted using special-purpose testing instrumentation rather than any specific communication device. It is intended to bypass the *cognitive* demands which would be present in unpracticed use of a device, thereby measuring the *motor* abilities which set an upper limit on rate in expert use. The second component of the system is a computer program which combines the outcome of a client's motor assessment with information specific to the use of each candidate device to derive an estimate of communication rate. Since this estimate is based on data gathered in assessment designed to establish the upper limits imposed on rate by the client's motor abilities, it is referred to as Motor-Determined Maximum Rate, or MDM Rate. In effect, this scheme is intended to model client's performance and its variation with the physical characteristics of devices. It utilizes this model as a means of conducting, in the domain of computer-based estimation, the tests of expert device use which are impossible to perform literally.

Preliminary Results — The assessment and rate estimation methods described above have, at this writing, been developed to the level of working prototypes. Substantial human subject testing has been and continues to be conducted with disabled and able-bodied individuals. Fourteen motor-disabled adult subjects and ten able-bodied controls have participated to date. Etiologies include head injury,

ALS, CP and stroke. Under present and future funding, more detailed experiments and further methodological refinements are anticipated.

In conclusion, it appears to be generally true that, while random variation is greater for motor-impaired than for able-bodied subjects, simple models succeed in extracting the reproducible average aspects of their performance. Reasonably reliable estimators of the dependence of movement time on task variables may be derived from clinically practical amounts of assessment data. This suggests that, while statistical validation of rate predictions remains to be accomplished, clinical feasibility of the investigators' methodology is confirmed.

A Needs-Features Spreadsheet for Communication Device Prescription

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Purpose — Spoken communication becomes difficult and even impossible for substantial numbers of people with neurological conditions which lead to impaired motor function. The large number and diversity of technological aids and personal computers with specialized software and control interfaces, and the real differences among these devices in terms of potential benefit to the disabled individual, have focused increased attention on improving the process of prescribing communication aids.

Progress — As part of this research, a computer-aided system has been devised to guide the clinician in identifying the device or devices which seem to offer maximum communicative benefit for each particular client. This system uses *client* information in the form of answers to an extensive questionnaire concerning the client's needs and preferences; and *device* information, in the form of a lengthy set of quantitative laboratory measurements and ratings, stored in computer disk files.

The output of this system for each client-device pair is a 'Benefit' score, B. The system is intended to be used as a way of evaluating many devices for each client. The B score, then, represents the relative value of each device for that client in terms of predicted communicative benefit. In practice, the assessing clinician enters answers to questionnaire items provided by the client and others and the system prepares a B score for each device the client would be able to use.

The basic tool used by the investigators for representing and manipulating the complex, many-to-many "mapping" of client Needs to communication device Features is a commercially available software package known as Lotus 1-2-3. Development of this worksheet and its clinical application requires, therefore the use of a computer which can run Lotus 1-2-3. We are using an IBM PC but the availability of Lotus 1-2-3 for other personal computers is expanding rapidly.

The worksheet has been tested and adjusted using questionnaire information from 20 non-speaking patients who use communication devices or boards. Measurements of the features of the communication boards and electronic devices used by these patients, in addition to the other devices which we have evaluated so far, constitute the device data files. An experimental study which will test the predictive value of the Needs-Features Spreadsheet along with other aspects of the Tufts-MIT Prescription Procedure began in April 1985.

An Optimal, Inexpensive Text Entry System for the Orthopaedically and Neurologically Disabled

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Purpose — The goal of this project is to devise a keyboard system based on an inexpensive digitizing tablet and customization via software that will facilitate computer operation by orthopaedically and neuromotorically disabled people. Customization is to be based on results of two lines of research: 1) an investigation of the sensitivity of users' key-to-key time to features of the keyboard's geometry; and 2) an evaluation of techniques of optimization to apply to the features of keyboards identified as important.

Progress — Software has been designed and is now being tested that allows the low-cost Chalkboard Powerpad to function as a field-specifiable keyboard for the Commodore 64, using only commercially available hardware. Keys of minimum ½ inch by ½ inch size are possible as well as selection strategies ranging from encoding and levels to multiple (discontinuous) representation of the same menu item. User-friendly screens are being revised to facilitate keyboard specification by people unfamiliar with computers.

Motor assessment of able-bodied and disabled subjects is being carried out by means of the reciprocal target tapping task and test panel. Previous work supports the hypothesis that inter-key distance and key size and in some cases angle of movement are major determiners of movement time. These data are being reanalyzed to characterize more precisely the effect of angle (direction) and identify interaction with distance and the patient's etiology. The sensitivity of communication rate to different arrangements of the alphabet for the subjects whose data have been collected is currently being examined.

A computer-based technique for adaptive design using a search algorithm known as a reproductive plan (modelled after genetic evolution) is currently being evaluated for its applicability to the capabilities and needs of the user.

Voice Control for Disabled Children

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Sponsor: Rehabilitation Engineering Department, Regency Park Centre for the Young Disabled

Purpose — Voice input is an emerging technology that will allow a vocal but physically limited person to operate a computer. A recent survey at this center indicated that there is a small but significant need for voice-recognition communication systems. The aims of this project are: 1) develop software to enable disabled school children to use voice input instead of a keyboard to access the Apple IIe computer; and 2) develop software to enable speech pathologists to train improved articulatory discrimination in speech impaired children.

Progress — In the preliminary phase the speed and accuracy of the Apple Voice Input Module (AVIM) voice recognition system will be tested for children with cerebral palsy and muscular dystrophy.

The experimental phase will develop a series of command programs for accessing and using the AVIM. Application programs to improve articulatory discrimination in speech impaired children will be developed.

During the concluding phase, results of this project will be published in a professional scientific journal. The programs developed in the project will be made available for purchase.

Computer-Aided Assessment for Communication Rate Prediction

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Purpose — A significant proportion of severely speech impaired people, of various etiologies, have a primarily if not uniquely *motor* obstacle to their use of language. In response to this need, many techniques and devices have been developed over the past 10 years to provide speech-disabled people with alternative means for communicating their messages.

Progress — Part of a system being developed for computer-aided prescription of communication devices for the motorically non-vocal is the use of an instrumented motor assessment in which movement times are recorded during reciprocal tapping tasks. A patient's data are used as the basis of a closed-form model of time vs. distance, target size and direction. This model is then used to derive computer-estimated predictions of communication rate with candidate devices. Experimental data from eight disabled device users show strong correlations between predicted and actual time/character.

The assessment instrument is based on a lap-sized portable computer. An input interface for up to eight capacitive or mechanical switch lines has been built in an attached enclosure. A two-foot square test panel provides an array of holes which serve to locate pairs of targets and couple them to the interface circuit.

F. Environmental Control Systems for the Severely Disabled

[See also pgs. 130, 134, 289]

Investigation of the Utilization of a Robotic Arm by Disabled Persons in the Workplace

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Sponsor: Wichita Rehabilitation Engineering Center

Purpose — Persons who have disabilities that limit arm and hand functions cannot perform the manipulative tasks often required on the job. In recent years, robots of various design have been developed for use in industry. The researchers of this project feel that the robotic arm has potential as a manipulative tool that would allow physically disabled individuals to perform tasks at the workplace not possible before.

Progress — Two small robotic arms complete with microprocessors manufactured and marketed by Microbot, Inc. have been purchased and members of the staff have become familiar with the programming and function of the devices. The

robotic device in question is of the type that maintains a base position but has all of the motions the human arm is capable of performing.

One work station at Center Industries Corporation, Wichita, Kansas, has been developed in the Boeing tinning room for the purpose of utilizing one of these robots. The center employs disabled persons in a workforce integrated with able-bodied persons. The robot picks small electrical resistors having wire leads one at a time from a holding fixture, dips the wire leads in a liquid flex, then in molten solder, and then deposits the part in an alcohol bath. The worker is required to see that the next part to be manipulated is in place in the holding fixture by the time the robot is ready to pick it in the normal cycle time. The worker also observes the operation to ensure quality and to use a special tool for periodically skimming dross from the surface of the molten solder. The proper depth of molten solder is maintained by the worker dropping small beads of solder into the pot when it is deemed necessary for the robot to achieve the proper depth of dip. Using the teach pendant, the programmer manually operates the robot through the positions required in the cycle of operation. The microprocessor remembers the steps in the cycle and repeats the cycle automatically when asked to do so by the operator.

A worker who is quadriplegic from cerebral palsy has operated this work station with success by sliding a single part on a slightly elevated platform to a receiving slot in the platform. Below the slot is a slide chute, the bottom of which is the holding fixture, or holding device, from which the robot picks the part.

After picking the part, the robot then moves to immerse the wire lead of the part in the liquid flux and then to the molten solder which is contained in an electrically heated pot. The part is then turned end-for-end and the dipping process is repeated prior to depositing the finished part in the alcohol bath.

Long-Term Health Care Applications for Robotic Technology

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — An applications research team was formed to find areas in which robot technology would fulfill a need. The objectives of this study were three-fold. First, we wanted to identify tasks that were amenable to augmentation or replacement by robotic technology. Second, we wanted to survey the attitudes of the administration and staff toward computers and robots. Third, we wanted to see if our training techniques for the VA/Stanford University (SU) Robotic Aid could be used successfully by older users and to see how their performance compared to younger users. Observations were carried out in the VA Nursing Home Care Unit (NHCU) in Menlo Park, California. The team was composed of an interdisciplinary group of fifteen individuals with 25 years collective experience using the VA/SU robot, including neuropsychologists, physicians, nurses, engineers, health services researchers, medical anthropologists, education specialists, and spinal cord injured veterans. Researchers silently and interactively observed activity in the NHCU during various shifts over a one-week period. NHCU staff also contributed their ideas for applications of robot technology.

Progress — In the area of robot applications, our team was able to identify 12 major categories with 54 sub-groups. The major categories for these tasks are

transfer-lift-transport, surveillance, housekeeping, physician assistant, ambulation, nurse assistant, physical therapy, patient assistant, depuddler (urine cleaner), and mental stimulation.

The second stage of our research examined, by questionnaire, attitudes of staff and administration in the VA NHCU. The questionnaire contained 111 questions of different types: likert-style, open-ended, and dichotomous (yes/no), and semantic differential. It was administered to the NHCU staff as part of our standardized orientation.

Of our 22 respondents, three were male and 19 were female. Their average age was 45 years. Sixteen had nursing related staff titles and the remaining six had other health and human service professional staff titles. Highlights of their responses include:

None use a computer at work.

- 95 percent agreed with the statement, *Computers have made living easier.*
- 86 percent agreed with the statement, *A robot could be useful in my job.*
- 96 percent agreed with the statement, *Robots have many beneficial applications.*
- 100 percent agreed with the statement, *Robots can be used to serve people.*

The results of our research indicate a very positive response to computer/robot technology. In general, all respondents described robots as *positive, valuable,* and *useful.* The clinical group was very enthusiastic toward human service applications of robotic technology. Informal surveying and interviews with the patients who participated indicated unexpectedly positive responses.

Two in-patient residents and two staff members (a nurse supervisor and a social worker) were trained on the VA/SU robotic aid. The two patients were male: ages 62, and 90; the nurse supervisor was male, age 35; the social worker was female, age 39. Each successfully completed at least two sessions with the robot. All users were able to complete our first standardized training task (picking up a cup with straw and giving themselves a drink) within one standard deviation of our mean task completion time of two minutes. (Subsequent to our study, two more patients were trained: male, age 61, and female, age 87.) For the first time in history, the study established the feasibility of successfully training older persons in a long-term care facility to use a robotic aid.

Interactive Evaluation of Artificial Vision with Robotic Aids for Individuals with Disabilities

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — There is a need to introduce a vision capability to the robotic aid by easing the visual monitoring task for the user and providing more efficient assistance. The objective of this project is to study the feasibility of introducing a commercially available vision system into an interactive robotic aid for disabled individuals. In an unstructured environment, the artificial intelligence available to all present vision systems is far too low to allow useful machine perception. We propose to supply the missing intelligence by guidance from the user who is always present in the interactive system and by coding objects in a manner which is machine readable. The communications between the robotic vision system and

the human will be designed to allow the user to supervise operations by adjusting system parameters as needed, by supplying object identification for the vision system when necessary, and by confirming important vision system operations. Disabled persons who would use a system of this type have been active participants in the design of this project from the beginning. Their ideas and suggestions are incorporated in order to have continual feedback on the user requirements at all stages of the project (Interactive Evaluation). Several code types have been analyzed and a useful code, based on geometric shapes, has been identified.

Progress — A General Electric vision system has been connected to an IBM PC and loading between the GE and IBM systems, allowing greater total memory storage limited only by the available hard disc space of the IBM PC. Preliminary computer programs allowing interactive operation of the vision system with a disabled user have been written. At some future time, these users may be able to say to a robot, "Give me the glass," and the robotic aid will identify, grasp, and present the glass. We expect that adaptations of the use of a coded environment will allow mobile robots to contribute usefully in home, hospital, and nursing home environments, especially when simple carry and delivery tasks are involved.

Training Methodology and Results for a Voice-Controlled Robotic Aid

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — When we began our research in 1981 there were no established protocols for teaching individuals to use voice-controlled assistive devices such as a robotic aid. Within the Interactive Evaluation methodological framework for evaluating prototype assistive devices, training procedures have been developed, standardized, and researched for a voice-controlled robotic aid. Training is important to the prototype evaluation research process because it: 1) provides a mechanism for systematic collection of user feedback; 2) allows researchers to incorporate user input into design and development; and 3) is critical to acceptance of any advanced assistive device—particularly computerized, interactive devices, such as a robotic aid.

While we have trained users from age five to age 90, our approach is based on andragogical and pedagogical principles. Key concepts include: self-directedness, learning readiness, immediate applicability, and problem-centered learning tasks. User training on this system is accomplished in five sessions which are one to two hours in length. During each session, the user reviews existing expertise, acquires new information, practices the lessons in both structured and unstructured manners, and finishes the session with a task that helps the user assimilate the entire lesson.

Progress — Over 125 users have been trained to use the VA/Stanford University Robotic Aid. A 200-page user's manual (containing both self-paced and trainer-paced instruction) has been developed and utilized by people with widely varied educational backgrounds. These educational levels range from less than a high

school degree to Ph.D.s, both technical and non-technical, and M.D.s. Feasibility of training a wide age, educational, and ability range has been shown.

Tasks for the robotic aid have been defined and studied in the following areas: *personal tasks* such as activities of daily living (ADL) including cooking, serving, salt shaking; *recreational tasks* such as board games and painting; *vocational tasks* such as opening file drawers, extracting files, and presenting them; and *therapeutic tasks* to improve visual monitoring skills and range of motion therapy.

Proficiency levels for robotic use have been established based upon these task areas. All users learned to pick up a cup within one hour of their first introduction to the robotic aid system. Drinking, feeding, serving, cooking, picking up and placing and fetching tasks for a robotic aid were named by 90 percent of the quadriplegic respondents.

Development of standardized training procedures for instructing trainers is currently underway. A 'peer training' program also is being developed to match user and trainer according to age or personal rehabilitation experience. Future studies are designed to assess our ability to optimize successful use of the robotic aid by matching a particular training style with a particular set of user characteristics.

A Formulation of the Interactive Evaluation Model

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The development of highly technical devices for disabled users requires continual feedback from the potential users to the project team designing the assistive device in order to assure that a useful product will result. This necessity for user input is the basis for the Interactive Evaluation Model. The Interactive Evaluation Model holds promise for minimizing project costs by introducing user feedback to increase the growth rate toward success of the project. In view of this fact, some quantitative formulation of the Model is necessary both to allow tests of this approach and to estimate the possible savings introduced by it.

The objective of this project is the mathematical formulation of the Interactive Evaluation Model. The formulation must account for user interaction within a team possessing the diverse expertise needed to research, design, and develop a highly technical assistive device. The aims of the formulation are to allow testable predictions of the model, to prompt specific questions that may refine the model, to identify data necessary to test the model, and to allow project design offering the highest probability of project success at minimum cost.

Progress — The mathematical formulation has lead to a simple set of equations giving the optimum number of class participants, including users, for a given project. The overall project costs can then be determined. In the simplest case the formulation determines that the optimum participation of a class of individuals should vary as the ratio of the class exponent to the class cost rate. Methods have been devised for estimating the class exponents and an illustrative example has been worked out based on our experience with medical care assistive aids. A

hypothetical project that operates at 230,000 dollars salary/yr without users can operate a 150,000 dollars salary/yr if potential users are included and provided the assumptions stated above are correct. We are now devising simple methods to test the validity of the Model and its formulation.

The results of this work can have deep significance in funding rehabilitation projects. The formulation of the Interactive Evaluation Model gives a prescription for designing a project to obtain success at a minimum cost by introducing users throughout the project life cycle. In addition, the formulation yields an outline for validating the Model. Should the Model prove correct, it offers a means for using monies available for publicly funded rehabilitaton projects as efficiently as possible.

Factors in the Design and Development of an Interactive Human-Robot Workstation

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Purpose — The Veterans Administration/Stanford University Robotic Aid is presently undergoing second generation development. The VA Merit Review Grant through which the project is funded, mandates design and development of the user interface where key specifications are based on the experiences of, and needs expressed by, the users of the first generation system. In the design of the interface to the robotic aid, the system designers must strive to maintain the relationship between the human and the robot while addressing human factors issues such as anthropometrics, task-related human factors, and value-related human factors.

An important subsystem of the human-robot interface is the user workstation; it is the physical component that links the user to the machine. General design parameters for a workstation include ergonomics, the functional requirements of the user, accessibility, aesthetics, safety, materials, integration into the user's environment, and connection to other systems. This particular system requires that the workstation: provide maximum access to the greatest number of users, both those with disabilities and the able-bodied; meet the needs of the technical development and clinical evaluation teams; and allow for multi-user interaction and easy group demonstration. The goal is a workstation that contributes to the overall effectiveness of the robotic aid through appropriate design and attention to interactiveness, accessibility, and autonomy (the degree of user control).

Progress — The first generation robotic aid served as proof of the concept that microprocessor-controlled human-scale industrial robots can be used by persons with physical disabilities in completing manipulation tasks. The objective of second generation development is to demonstrate the utility of a human-service robotic aid and to deliver the technology needed to make robotic manipulation aids broadly useful. Evaluation and testing of the robotic aid with disabled users has been performed according to the Interactive Evaluation Model. Over 90 people, 23 of whom are spinal cord injured, have been trained to use the first generation system in the past two years. User-specific training has focused on activities of daily living, recreational and vocational tasks such as preparing a meal, playing board games, and opening a file drawer to retrieve a file.

The clinical system employs voice as the primary input and output channel. Other input devices include a teachbox and a standard keyboard for use by the system operator in programming motion sequences, and a pushbutton for emergency stops. The sensory capability of the clinical system is limited to a few touch-activated microswitches located in the gripper. The second generation lab system includes: improved speech synthesis and recognition units; VIDOF for six-axis control of the robotic aid; the Ultrasonic Head Control Unit for two-axis control of the mobile base and the graphics screen cursor; a series of programmable switches to be dedicated as needed; a keyboard; and, a television camera to provide real time environmental information. A high resolution graphics display will be used, in addition to a diagnostic display and a video monitor, to enhance the presentation of system states to the user. The sensing capabilities of the robotic aid will greatly increase in the second generation, lessening the control burden on the user while increasing the utility of the robotic aid as new tasks can be attempted.

The design of this workstation has been likened to the design of a vehicle dashboard. Both require that special attention be given to the forward visual field of the driver or operator while maintaining the visual field of display, to hand (or mouthstick) reach for control action, and to knee and leg (or wheelchair) clearance for accessibility and comfort.

Future Plans — Iteration and refinement of design concepts are expected. The initial prototype, under construction now, will be used with the laboratory system. Following system debugging and further development, the updated robotic system, mobile base and workstation will be transferred to the clinical group for evaluation and user trials. This cycle of development and evaluation will continue until the delivery of what will hopefully be deemed a practical human service robotic device with an appropriate human-machine interface.

Design of Bathrooms, Bathing Fixtures, and Controls for Disabled and Elderly Persons

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this research is to complete the development of four bathing fixtures designed by the investigators. Each of the fixture designs is to be evaluated through usage by disabled and elderly subjects, modified as necessary to meet usage and production criteria, and finalized for manufacturing. The four fixtures under development are: a cushioned shower (with vinyl skinned padded surfaces); a shower with two seats; a roll-in stall shower with a wall mounted seat; and a two-piece roll-in shower.

Each shower design responds to the physical characteristics of certain types of disabilities. For example, the cushioned shower has a padded surface to reduce the tendency for skin breakdown and a contoured seat area to provide trunk stability; the shower with two seats is designed for use by right or left hemiplegics or by individuals who require assistance during bathing; the roll-in shower with a wall seat is designed for use by persons who can transfer from a wheelchair or by persons who enter the shower in a standing position; and the two-piece roll-in shower is designed for use by persons who use a shower type wheelchair rather than a shower seat.

Progress — Evaluation and design methodologies are being used in this project. The evaluation of the four fixtures has been completed. This was based on quantitative and qualitative analysis of user performance, user safety, and accomplishment of bathing tasks. Task accomplishment was measured by success or failure of tasks overall user performance, time-motion studies, and user safety as determined by behavioral observation. User satisfaction was determined from a post-trial interview. The pending design modifications are based on the results of the fixture evaluations.

The evaluation of the shower fixtures was conducted through observation of forty-four disabled subjects taking showers. For each subject tested, a pre-trial questionnaire was filled out that documented current bathing habits, including safety, frequency, and method of bathing. Each subject was given instructions verbally and through an illustrated brochure that showed how to use each fixutre. All fixture trials were videotaped for later analysis of movement. Subjects used only the fixtures that could (in the opinion of the research team and the occupational therapist) safely accommodate their physical capabilities. Following the use of each fixture a post-trial interview was administered to determine the subject's perception of the fixture in terms of safety, comfort, ease of use, and overall acceptability. Perceptions were recorded by the occupational therapist using a five-point scale.

Analysis of the visual and coded data was done through frequency studies and the determination of means and standard deviations. Visual data from the video tapes were translated to coded data for analysis. Transfer, bathing, and exiting tasks were analyzed both to determine success/failure and to document any hazardous movements or conditions.

Preliminary Results — The evaluation indicates that the four fixture designs as a group can safely accommodate a wide variety of physical disabilities. Of the three fixtures that are usable by persons capable of wheelchair transfers, the roll-in shower with wall mounted seat was used by the most number of subjects. Subjects with limited range of motion in the lower extremities often had difficulty using the cushioned shower largely because in the final bathing position the feet were elevated. For most subjects the seating positions of the roll-in shower with seat and the two seat shower were preferred to the seating position of the cushioned shower. The two-piece roll-in shower was slightly undersized for some subjects causing problems in closing the shower curtain.

Findings of the evaluation are now being used to redesign each of the four designs. The two-piece roll-in shower is being lengthened to better accommodate a tall wheelchair user and the floor of the fixture is being modified to accept a new grating design. The cushioned shower will be modified so that the foot rest area is not as high off the floor and the grab bar location and design is being changed. Cushioning will be applied to the wall mounted seat to better accommodate persons with loss of sensation. The two seat shower is not expected to be modified at this time.

Future Plans — Following the modification of each of the three showers, the new prototypes will undergo a limited evaluation. Following this testing the completed shower designs will be available for marketing.

Ultrasonic Head Control Interface (UHCI)

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Purpose — Successful development of a device that can overcome current interface shortcomings would be of significant value to severely injured individuals who wish to control their mobility or communication in a socially acceptable and aesthetically pleasing manner. In particular, the existence of a device that operates at a distance without the necessity of mechanical contact, uses a control site not required for sensory input, and is easy to learn and use would be an ideal solution. Other features such as modular construction, low cost, the ability to accommodate many users, and self calibration would contribute to the universality of the interface, and thereby stimulate its widespread use.

Ultrasonic distance ranging requires no physical contact with the object of interest. Used as an interface, a user would not feel 'wired-up' with a device incorporating this technology. The investigator hypothesizes that an array of distance ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility and communication devices.

Progress — In this project, two Polaroid ultrasonic distance ranging sensors are employed. They emit inaudible sound waves that propagate through the air until reflected by an object. A portion of the echo signal returns to the transmitting sensor and is detected by the associated electronics. The measured time from transmission to the reception of the echo is proportional to twice the distance from the sensor to the object. In this rehabilitation application, two separated sensors are directed at the user's head. The two distance ranges, one from each sensor to the head, and the fixed separation of the sensors describe a triangle whose vertices are the two stationary sensors and the user's moving head. A geometric relationship allows the offset from the base line and center line of the two sensors to be calculated. This information is then used to map the user's head position onto a two-dimensional control space.

In operation, users of the Ultrasonic Head Control Interface (UHCI) merely tilt their head off the vertical axis in the forward/backward or left/right directions. Their head position can produce the same effects as a joystick. Both can be used to control devices to which they are attached such as a wheelchair, a communication aid, or a video game.

The main advantage of this type of interface is that no mechanical contact between the sensors and user's head is required. This effectively separates the user from the device being controlled. Users should not feel confined by devices around their face or body with this unit, as frequently occurs with other interfaces. The use of the remote sensing ability of the UHCI should result in rehabilitaton devices that are socially acceptable and cosmetically pleasing.

Preliminary Results — UHCI have been installed on two electric wheelchairs. The first is an E&J Model 3P equipped with a reclining Recaro seat and is in use in France by a quadriplegic woman. The second is mounted on an Invacare Roll IV with a Solo Products Power Pack and is being evaluated by spinal cord injury patients at the VA facility. Both units have been operational since June, 1983. User evaluation has been performed with ten quadriplegic individuals. After a short

demonstration and training session, they were transferred into the chair and most were able to successfully navigate the chair without problem. Users state that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs.

A generalized interface for a robotics application also has been developed. With the UHCI, the robot user will be able to select tasks and control the operation of a mobile mechanical arm. Specifically, the path for the vehicle will be specified by 'drawing' its planned trajectory on a CRT with head motions.

Future Plans — Another robotic application of the UHCI is being pursued. Used in conjunction with a robotic arm, it will provide control of its hand position. The user's head position will be used to control two degrees of robotic arm freedom. Compared to the current voice recognition method, a faster and more interactive manipulation of the hand is anticipated.

In a communications application, the UHCI will monitor the user's head position and control a moving light cursor in an X-Y matrix of letters and words. Selection is then accomplished by pausing on the desired square. A commercial joystick-operated aid has been donated for this work.

A technical manual documenting the work on the UHCI, including background material, electronic schematics, computer program listings, explanations, and illustrations has been compiled. Its intended purpose is to provide information that would allow a technically knowledgeable and adequately equipped person to construct a UHCI and apply it to the control of devices such as powered wheelchairs. This manual has been made available to over 40 interested parties, who are considering the UHCI for research or commercialization.

Within the VA, a Request for Evaluation has been submitted and approved. Funds will be made available for the commercial production of four units which then will be evaluated at VA medical centers throughout the country. A decision will then be forthcoming regarding the desirability of purchasing additional electric wheelchairs using the UHCI for disabled veterans.

Development of Environmental Control Units for Disabled Veterans

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Purpose — A large population of elderly veterans and civilian population are confined to a single room, such as an extended care hospital or nursing homes. Many people in this situation need help in simple tasks such as operating lights, TVs, radios, beds, and other appliances. An environmental control would allow them to perform these tasks themselves rather than having to call for assistance.

The Electronic Industries Association (EIA) has a task group developing standards allowing remote control of lights and appliances within a room for the able-bodied. If these standards are implemented, this would allow equipment from different manufacturers to work together.

Progress — This project will research the desirability from both a technical and economic viewpoint of using these emerging specifications in an extended care facility. If these components can be used, system cost can be minimized because only a controller, usable by the handicapped, would need to be designed.

The Development of Environmental Control Systems for the Severely Physically Disabled

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Sponsor: Scientific and Research Trust of Central Remedial Clinic

Purpose — Severely physically disabled children and adults can control their own environment by the application and adaptation of technological development, providing they can reliably operate a single switch. In this way, they can be more truly independent.

Recent developments (especially in the United States) have shown that microcomputers can be used as controllers to send switching signals to slave devices through the in-house main wiring. This removes the need for hardwired interconnections. To date, these systems have, in the main, been developed for use in conjunction with American electricity supply standards and Bell telephone switching protocol. As yet, little or no work has been done on developing similar systems for use in Europe. By making the relevant hardware and switching modification, this project will develop showcase systems for use in Europe, in addition to developing special systems to suit individual needs. It is expected that these systems will have universal applicability throughout Europe.

Reinforcement of Voluntary Head Control

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Purpose — Nonambulatory patients with hypotonic neck and head muscles are subject to additional complications because of their limited field of vision, feeding, speech, and other difficulties.

Progress — This project intended to improve the strength of the head and neck muscles by using a music biofeedback device. A mercury switch attached to a hat was designed to trigger music in earphones worn by the patient as soon as his head reached within 30 degrees of vertical. Once the music of choice of each of four patients was determined, half-hour sessions on a daily basis were conducted for two weeks. Preliminary data show that the total time the head was within 30 degrees of vertical improved by an average of 57 percent at the end of two weeks, with substantial carry-over improvement for other activities during the day.

Voice-Operated Appliance Control

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Purpose — Recent advances in voice recognition technology have provided low-cost integrated circuits capable of speaker-independent recognition of up to 16 words. This center has developed two devices to demonstrate the usefulness of this technology to disabled people.

Progress — One device is called the voice-operated appliance control (VOAC). The VOAC allows its user to operate up to 256 electrical devices with three simple voice commands: "go ahead," "search" and "stop." "Search" causes the

VOAC to sequentially display its three basic control modes: "all on," "all off," and "select." When the desired mode is displayed, it is selected by saying "stop." The user executes the mode by saying "go ahead." Selecting "all off" or "all on" will turn all units off or on. Selecting "select" allows control of individual units. "Faster" and "slower" control the display rate at all times.

In the select mode, the VOAC sequentially displays the numbers of available units. A unit is selected by stopping the display when the unit's number appears. When the unit has been selected, the VOAC sequentially displays functions available for that unit. Possible functions are "on," "off," "bright," "dim," and "momentary." The latter will turn a unit on until the user says "stop." As before, functions are selected by stopping the display and saying "go ahead."

Training Capuchin Monkeys to Serve as Aides for High Level Quadriplegics

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This project is an ongoing attempt to refine the procedures by which capuchin monkeys are trained to serve as aides for high level quadriplegics.

Progress — Work is underway to meet the following objectives:

1) Approximately three-fourths of the training procedures used in teaching a basic repertoire of skills have been standardized and described in a 100-page illustrated training manual as well as instructional videotapes.

2) A solid food dispenser designed to replace a liquid reward dispenser underwent field testing in the Fall of 1985.

3) Seven high level quadriplegics are now using simian aides. One cerebral palsy patient was paired with a simian aide in the Fall of 1985.

4) A breeding colony was established in 1985 at the Mannheimer Primatological Foundation in Florida to produce 20 to 40 infant Cebus per year. A breeding colony also has been located in Argentina and 16 female infants were purchased during the Fall of 1985.

6) A non-profit organization has been established to apply the knowledge gained from the simian aide research. Financial support for the organization has been secured via a corporate sponsor and as mature animals become available, placements of simian aides will begin at a rate of 20 to 40 per year in 1987.

7) An evaluation of the simian aide research is currently being conducted by the evaluation unit of the Department of Rehabilitation Research and Development. A second evaluation by the New York University Spinal Cord Injury Research Unit is planned for January of 1986.

8) A market survey testing the preferences of high level quadriplegics for simian aides versus robotic arm work tables was scheduled for the Fall of 1985.

9) An experimental program for teaching college students how to train monkeys was initiated in September of 1985. Efficiency and cost-effectiveness will be evaluated over the next two years.

10) Canada, Argentina, and Israel are now beginning their own simian aide programs; training material and primate selection information is being provided to them at no charge.

Wheelchair Control and Robot Arm/Work Table System for High Spinal Cord Injured Persons

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Purpose — The objective of the project during this period (June 1984 through March 1985) has been the completion of an important phase of clinical evaluation of the Robot Arm/Work Table System at the Spinal Cord Injury Services at the VA Medical Centers in Richmond, Virginia and Cleveland, Ohio. In parallel with this testing, two important engineering improvements were made to the system. Development of a new, self-adjusting chin controller of the wheelchair was completed, and three axis simultaneous motion capability of the Robot Arm was achieved. Details of over two years of clinical testing were given in the technical article in the January 1985 Volume of the Journal of Rehabilitation Research and Development.

That report includes the experiences of users who evaluated the equipment during the first six months of the current report period, as well as those of users who evaluated the equipment during the previous year and a half. The current report summarizes those results and the results of an additional user who evaluated the equipment during the remaining months of the current report period.

Progress — Through December 1984, 20 male quadriplegics between 21 and 60 years of age at evaluation had been involved in the evaluation in three geographical areas, i.e., Baltimore-Washington, Richmond, and Cleveland. They ranged from five to 26 years between time of injury and evaluation. The levels of injury ranged from C-2 to C-5. Individual accumulations of time actually working with the equipment ranged from one hour to over 100 hours; 316 meals were eaten by these individuals using the Robot Arm. Among the nine quadriplegics who tested the equipment at the Richmond VAMC, seven indicated that they found the equipment gratifying to use, especially for self-feeding. Among the seven quadriplegics who tested the system at the Cleveland VAMC, none found the system useful. They cited a number of reasons. Regardless of the differences in overall assessments, agreement existed on two general problems.

One problem was lack of adequate adjustability of the wheelchair chin controller to enable the operator to compensate for changes in his posture in the wheelchair. This accounted for a degree of incompatability of the system with reclining users. There were also reliability and maintenance problems with the original design. The second problem was slowness of the Robot Arm in accomplishing repetitive tasks such as self-feeding. Both of these problems were addressed and engineering design changes were made to the hardware.

A new chin controller was designed to interface with the E&J Model 3P wheelchair. This design change addressed problems such as the lack of ruggedness, too much head motion required, lack of provisions for readjustment by the user, and too troublesome for attendants to mount and align on the wheelchair frame. In order to speed up the cycle time of the Robot Arm, a new multiaxial controller was designed based on the use of the 6809 microprocessor. The 6809 microprocessor and its associated software allow additional flexibility for programming task trajectories and give the system greater operational reliability.

The user who evaluated the equipment during the final months of the current report period was a 27-year-old C3-5 quadriplegic with a motor residual of partial function of the deltoids, one pectoralis major, and one biceps. With the exception of the new multiaxial capability, he evaluated the Robot Arm/Work Table with all subsystems including an electric wheelchair with the new chin controller. He worked with the equipment over a three-month-period in the OT facility at the Richmond VAMC. He ate 24 complete meals with the Robot Arm. He had very positive comments about all aspects of the system and specifically about the new wheelchair chin controller's responsiveness and self-adjustability.

Future Plans — Clinical evaluation of the new simultaneous multiaxial motion feature for the Robot Arm is anticipated during the next report period.

G. Wheelchairs, Including Seating and Controls

[See also pgs. 110, 130, 147]

The Sunburst Tandem

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Purpose — Individuals with various physical disabilities resulting from paraplegia, low level and incomplete quadriplegia, amputation, muscular dystrophy, multiple sclerosis, stroke, cerebral palsy, blindness, etc., who endeavor to live healthy and meaningful lives may benefit greatly in their physical, psychological, and social well-being from participation in recreational activities with family and friends. With the development and subsequent availability of an appropriate design, tandem bicycling is one highly integrative activity which will promote participation by individuals with disability.

A tandem bicycle to be shared by individuals with and without disability will literally provide a vehicle for integrated mobility and recreation. On such a tandem, many excluded from the revitalizing activity of bicycling will experience the freedom, exhilaration and accomplishment of riding a bicycle.

The pre-production development of a single rider arm-powered bicycle, the *Handbike*, is essentially complete. As a spin-off from the development of the *Handbike*, the first prototype of a tandem called the *Handbike Tandem* for disabled and able-bodied to share, was completed in June 1983. Conceptually, the configuration of the *Handbike Tandem* consists of merging the *Handbike* in the front with a standard bicycle in the back. In the interest of independence and equality, this first tandem prototype was designed to be ridden by one rider alone in the front or back position. The experience gained by the development of the *Handbike* and the *Handbike Tandem* has led directly to the design of the second tandem prototype called the *Sunburst*.

Progress — Although similar to the *Handbike Tandem* in rider configuration, an alternative drive system and vehicle identity was planned for the *Sunburst*, completed in June 1984. On the *Sunburst*, arm- and foot-powered recumbent cycling in the front combines with a standard bicycle in the back.

The back rider steers through a remote linkage from the handlebars to the front wheel, and pedals in a standard bicycling posture. The front rider sits in a recumbent position and powers with any combination of arms or legs. With the *Sunburst's* configuration (as opposed to a standard tandem), both riders have a clear view ahead and find it easy to converse. The back rider controls the rear caliper brake with a hand lever. In addition, both riders activate the front hub brake by backpedaling.

The *Sunburst* riders move as one, combining their pedaling effort and balance to their best ability. The front cranks directly couple allowing the front rider to assist or passively exercise his or her own less functional limbs. For those who prefer not to either actively or passively move their legs, a leg rest attaches to the seat. A freewheeling system allows the front rider to stop pedaling and rest while the back rider continues to pedal. If a rider is unable to pedal at all, he or she may just go along for the ride. When the *Sunburst* comes to a stop, the front rider can lower a secure kickstand. The front drive system and seat are detachable, yielding a single rider bicycle, when desired. The front seat also may be converted into a cargo area increasing the versatility of the *Sunburst*.

With the front position designed to appeal to able-bodied riders as well, an individual with disability has the dignity of riding the *Sunburst* in the same position as able-bodied friends. In addition, the visibility of the *Sunburst* in the community heightens public awareness by drawing attention to our common desire to be mobile and to participate in recreational activities, unmitigated by disability.

A design documentation manual is being assembled as a vehicle for technology transfer of the *Sunburst* to manufacturers. Further performance and mechanical evaluation is needed to help assure that the most worthy tandem product will be available to individuals with disability.

Optimal Biomechanical Design Development of Arm-Powered Mobility Vehicles

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Individuals with lower limb disorders and spinal cord injuries are looking for better devices to enhance their mobility and through it the quality and degree of independence and societal integration to which they are entitled. As far as arm-powered vehicles are concerned, few alternatives to the wheelchair-handrim device are currently available and precious little research effort has been made to fine-tune the rider to his mobility aid. A need exists, therefore, to better understand the operator-vehicle interface in order to design better arm-powered vehicles that are ergonomically attractive, economically feasible, and help to optimize the biomechanical efficiency of the arm-cranking tasks.

If we are to optimize arm-powered vehicles we must conduct research that develops the best vehicular drive mechanism that successfully incorporates neurophysiology and biomechanical control of the upper limb as it interfaces to a given drive mechanism. Only then will the tens of thousands of disabled individuals be afforded the opportunity to have maximum utilization of their mobility access.

Progress — Modern control theory and, in particular, optimal control theory, have been used successfully for decades by the aerospace and military communities as important engineering tools for the development of advanced designs which optimize device performance. Advanced modeling efforts using digital computers have enabled engineers to explore design parameter changes quickly, without resorting to expensive prototype development and re-engineering. More recently, attempts have been made to apply these same optimization and modeling techniques to biological systems, in particular to open-link kinematic structures which propose to model human locomotion and jumping.

It is the major hypothesis of this proposed research that modern control theory, when coupled with careful human biomechanical performance measurements, can lead to nearly optimal arm-powered drives for use in mobility and recreational vehicles for the disabled. A tractable biomechanical model may then be developed for the upper limb as it applies to a broad spectrum of arm-cranking tasks. We can use this model to develop optimum design parameters for various arm-cranking mechanisms (e.g., rotary, eccentric, and linear drive schemes).

Pressure Sores, Blood Rheology, and the Mechanical Properties of Soft Connective Tissues

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Sponsor: Scottish Home and Health Department

Progress—

Pressure Sores. Work in pressure sores centers on the prevention of sores by the detection of patients at risk and the provision of specialized equipment. There is a major research program in the measurement of the mobility of elderly patients both in chairs and in beds. Mobility measurements are made by supporting the devices on low profile load cells; data conversion, logging and analysis are carried out by an on-line microcomputer. The initial work on bed mobility has been completed and has demonstrated useful and simple parameters for selecting those patients at risk of developing pressure sores. Work on patients in chairs is at an earlier stage.

Blood Rheology. There are studies of blood rheology and transcutaneous oxygen tension in patients with diabetes. The aim is to elucidate the connection between abnormal blood viscosity and red cell deformabilty in these patients and the tissue oxygenation status. Patients with poor and good diabetic control and quantified neuropathies will be investigated. Initial results have been obtained on the blood viscosity and red cell deformability and the major integrated program will be commencing imminently.

Work is also underway on the relationship between blood viscosity and red cell deformability and the outcome of patients who have suffered an acute stroke. Previous studies on the connection between hematocrit and outcome indicated that elderly patients with an abnormally low or abnormally high hematocrit did worse than patients within the normal range.

The Mechanical Properties of Soft Connective Tissues. There is a continuing research effort in the characterization of these tissues, with the emphasis being on skin.

Seating System for Patients with Multiple Spinal Deformities

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Sponsor: Louisiana Department of Health and Human Resources

Purpose — Patients who are severely developmentally disabled exhibit scoliosis, pelvic rotation and obliquity, scissored legs, spasticity, and hyper-reflexia. After several years of experience, a systematic management program was developed incorporating a multidisciplinary approach. The management program consists of three phases: pre-surgical bracing, spinal surgery, and post-surgical bracing.

The role of pre-surgical bracing is to contain the deformity to manageable levels during the growing years so that once the deformity stabilizes it does not present a high-risk surgical case for the second phase. After spinal instrumentation with Luque technique, a different seating system is designed for the patient allowing him to stabilize in the desired posture.

Progress — Both pre- and post-surgical seating systems were designed with corrective rather than adaptive principles. They incorporate a maximum surface contact with the patient and contour to normal posture of same size. The backrest provides continuous contoured lateral support from below the axilla to the hip. The seat also has lateral supports to prevent rotation and a built-in abductor post to prevent lower extremity scissoring and to stabilize the pelvic anatomy. All padding material consists of Action Gel to provide pressure equalization. The seat and back braces are attached to a regular wheelchair frame with quick-disconnect latches to preserve portability and may be angulated relative to each other as may be necessary for the individual patient. Generally, hip and knee flexions of less than 90 degrees were found to provide substantial relief for hyper-reflexia (extensor thrust).

Wheelchair Seating Effectiveness and Wheelchair Performance

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Sponsor: Regency Park Centre for Young Disabled

Purpose — Many disabled children spend a large part of each day in an electric wheelchair. They need comfortable, supportive seating and a reliable wheelchair that meets their needs. The effectiveness of new seating systems has not been objectively assessed, and the reliability of electric wheelchairs needs to be improved.

Aims are: to develop assessment procedures for wheelchair seating systems in terms of cost, comfort, cosmesis and function, and to evaluate six new special seating systems using the protocol established; to conduct performance measurement studies on electric wheelchairs; and to use quantitative procedures to improve client/wheelchair matching, using the results from the above.

Progress — This study involves two concurrent streams of work, concerned with seating effectiveness and wheelchair performance.

During the preliminary phase, protocols will be developed for the comparison of alternative special seating systems. Several new seating systems, such as matrix supports and foam-in-place methods, have recently become available. Five each of six alternative seating systems will be purchased for fitting to groups of subjects matched as closely as possible for age, sex, diagnosis and degree of impairment.

In the experimental phase, 30 cerebral palsied children will be fitted with special seating systems and each will be evaluated over a three-month-period from the date of fitting.

In the concluding phase, the results of the evaluation, which will include prescription criteria, will be published in a professional scientific journal, and an instructional course on modern seating techniques for cerebral palsied children will be conducted.

In the preliminary phase, a protocol data measuring/logging system will be purchased, adapted and mounted on an electric wheelchair and an adjustable ramp will be built for testing the static and dynamic stability of wheelchairs.

In the experimental phase, the data logger will be used to analyze patterns of wheelchair usage, which will be related to problems experienced in wheelchair use.

During the concluding phase, the results of this study will be made available to the Standards Association of Australia and a professional scientific journal, and we will work with wheelchair manufacturers to improve the design of electric wheelchairs, control interfaces and wheelchair seating.

Many children with cerebral palsy spend a large part of each day seated in a wheelchair. Inappropriate seating is a major contributor to the problems they experience in balance and comfort. Widely accepted seating guidelines in cerebral palsy have not been scientifically validated.

The number of children at this center using electric wheelchairs has increased from two to 87 in the last nine years. There are, however, currently no standards or laboratories used in Australia for testing the performance of wheelchairs, and consequently the incidence of breakdowns is high. An internal report at the center indicates that annual maintenance costs on some makes are up to 30 percent of purchase price.

Preliminary Results — This project will result in improved seating for disabled children, at this center and elsewhere. It also will result in the establishment of an Australia-wide wheelchair testing facility at the Regency Park Centre for Young Disabled.

Development of Wheelchair Standards

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — This work is being carried out by contract with the Rehabilitation Engineering Society of North America (RESNA) with administrative assistance through the Director of Research, Paralyzed Veterans of America. The work has been in progress for several years but under this contract for the past year. Regular meetings of the full committee are held on a six-month basis plus international standards meetings and ad hoc committee meetings on special projects. The representatives of RESNA and the committee attend the international working group meetings working to establish the standards through the International Standards Organization (ISO).

Research and testing are carried out in the laboratories of the University of Virginia, University of Tennessee, Stanford University and Palo Alto VAMC, VA

Rehabilitation Engineering Center Laboratories and the Laboratories of Everest and Jennings and Rolls-Invacare.

Representation in the committee covers a broad spectrum of persons interested in wheelchair and wheelchair problems from the academic community to the manufacturers of wheelchairs and interested consumer groups, therapists from a number of Spinal Cord Injury Units and representatives of the Veterans Administration and the Food and Drug Administration.

Progress — Testing has been completed and the ISO accepted standards determination of static stability. Work has been completed and submitted to the International Standards Organization for: the determination of the efficiency of brakes; determination of energy consumption of electric wheelchairs; determination of overall dimensions, mass and turning space; determination of maximum speed, acceleration and retardation for electric wheelchairs; climatic tests for electric wheelchairs; determination of the obstacle climbing ability of electric wheelchairs; test dummies; and determination of the coefficient of friction of test surfaces. This committee has been a major contributor in the areas of the static testing, dynamic stability, maximum speed and acceleration, seating dimensions, static and impact fatigue testing, and determination of the coefficient of friction.

Items on which testing has not been completed, that is, the determination of dynamic stability of electric wheelchairs, determination of seating dimensions, static impact and fatigue strength for manual wheelchairs, and determination of tracking characteristics of wheelchairs, is well underway and it is anticipated that the work will be accomplished within the next eighteen months and that this will result in acceptance of standards that will be identical for ANSI and ISO.

Work is being done on the appropriate disclosure of the results of these testings and standards as would be applied to wheelchairs. The appropriate disclosure forms are being developed. It is anticipated that this will take the form of disclosures that will be of use to consumers and practitioners in comparing various wheelchairs to determine which would be the most appropriate for a given individual. The majority of these standards will be of a descriptive nature and not of a restrictive nature. It is expected that all the goals of this project will be easily completed within the remaining two years of the contract.

Developing Safety Standards for Wheelchair Occupants in Vehicles

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Sponsor: Department of Transport, Government of South Australia

Purpose — Testing of vehicle restraints for wheelchair occupants has revealed that commonly used methods are unsafe. Previous work at Regency Park Centre for Young Disabled led to the development of a crashworthy restraint system for wheelchair occupants and, more recently, the broader issue of safety standards has been addressed.

The use of effective restraints for wheelchair occupants in vehicles is hindered by several factors: some types of wheelchairs are clearly unsuitable for vehicle seating and very few wheelchairs have been designed for use in vehicles; the wide variety of wheelchairs in use complicates the design of restraints; vehicles do not have suitable anchor points for wheelchair occupant restraints; there are no

accepted standards for wheelchair occupant restraints; and no information or advice is available to prospective users or buyers of wheelchair occupant restraints.

Progress — The following initiatives are being developed to overcome these difficulties: an illustrated booklet to inform prospective users and buyers of the need for restraints, the choice of suitable wheelchairs, and related safety issues; an informative videotape, similar to the booklet in content; a comprehensive set of design and performance requirements for wheelchair occupant restraints; a code of practice, to be implemented in South Australia, establishing a scheme to ensure that restraints satisfy those requirements, are correctly installed, and that vehicles are adequately reinforced; and an Australian standard for wheelchair and occupant restraints is in preparation. These developments will provide protection for wheelchair occupants travelling in vehicles and facilitate transport of severely disabled people.

Skin Blood Flow Under External Loading

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Although it is generally accepted that alterations in skin blood flow are associated with the onset and development of pressure sores, demonstrations of that association are nonexistent. The question is "Does skin blood flow response to external loading differ in patients who develop pressure sores from that of patients who do not?" If such differences do exist and can be easily measured, then patients might be assessed upon hospital admission with regard to pressure sore risk, so that appropriate precautions may be initiated as necessary.

Progress — In order to ensure the measurement and proper grouping of each of the important parameters, a dimensional analysis was performed which indicated that the change in skin blood flow under an external load applied over a bone could be represented mathematically.

Early experimental work has been focused on gaining experience with the laser doppler instrument and its limitations. It was found that applicaton of external loads to the skin caused a decrease in DC level of the instrument, which in turn produced an artificial decrease in indicated flow level. The instrument was subsequently modified to prevent this effect.

Preliminary experiments have been carried out on several able-bodied and spinal cord injured subjects with the subject in a side-lying position with known weights applied to load the skin over the proximal femur by means of a cylindrical fixture which houses the laser doppler probe. Blood flow occlusion was not seen even at extremely high external loadings. Additional investigation indicates that the laser doppler does indeed indicate zero flow if all motion ceases, which does not necessarily occur when net blood flow decreases to zero. Therefore, the problem we now face is that of determining the nature of the motion that is being detected by the laser doppler at high applied pressures.

Both cylindrical and spherical indentors have been machined which house the doppler probe with a flush surface to the skin and also permit direct application of

the loading weights to a built-in flat platform. Skin displacement is measured by marking the shaft of the load applicator for each applied load.

Preliminary Results — Results to date show a decrease of skin blood flow with applied loading in all cases, but do not indicate skin blood flow occlusion even at high pressure loadings. We are investigating the source of this residual signal, which we believe indicates some type of motion other than blood flow since all vessels should be occluded at these levels. The indicated residual motion could be tissue creep, fluid leakage, or other cellular motions, and will be investigated using either animal or simulation models. In addition, we are preparing to compare the output of our instrument with that of a laser doppler instrument from another manufacturer since the signal processing of the two units is somewhat different. These comparisons will be performed on human subjects using the protocol described above.

Skin displacement measurements are unaffected by the above instrument characteristics and have yielded findings which indicate that the tissues overlying the proximal femur become stiffer with age (higher pressure required for the same displacement), regardless of spinal cord injury. The tissue characteristics are found in all cases to be nonlinear, becoming stiffer with increased loading.

Future Plans — Systematic testing of able-bodied and spinal cord injured subjects in the four groups specified above is planned as soon as the proper correction of the doppler flow data can be established. It is planned to test correlations between skin blood flow response to pressure and shear loadings and the occurrence of pressure sores in each of the four groups to be studied.

Seat Cushions for the Paralyzed

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Pressure sores continue to be a problem area for spinal cord injury and geriatric patients. The role of shear forces developed in sitting with respect to trauma in the region of the ischial tuberosities may be significant in pressure sore causation. Prior results have shown that cutaneous pulsatile flow within the buttocks of seated paraplegic subjects is considerably smaller in magnitude than that of normal subjects. It also has been shown that the sitting shear force developed by paraplegics is considerably larger than corresponding measurements of normal subjects. At issue is the relationships, if any, between these factors; what role does shear force play in producing ischemia in those who are paralyzed?

A second goal is the development of a clinical device capable of monitoring cutaneous blood flow at the patient support surface interface. Such a device is to be compatible with cushions, mattresses, etc.

Progress — A hard seat equipped with instruments measuring pressure, shear and cutaneous pulsatile blood flow was augmented with computer devices yielding a harmonic analysis of plethysmographic waveform. By comparing ratios of harmonic intensity (2nd and 3rd) to that of the fundamental vasoconstrictive

tendencies are perceived and measured. To date, 18 normals and nine paraplegics have been tested. Sought is that degree of arteriolar blood flow inhibition, if any, arising through shear and paralysis.

A prototype fiber optic sensor of cutaneous blood flow has been completed and tested. Offering little thickness and considerable flexibility, such a device might be employed to determine those patients prone to cutaneous blood flow occlusion at unusually low seating pressures. Cushion evaluation is also a prospective use.

The current prototype, when tested against a conventional mercury strain gauge sensor, reveals deficiencies in the depiction of waveshape contour. Specifically, differences exist in rise time (acceleration) and dicrotic notch portrayal. Electronic filter and photo sensing devices contained within the fiber optic system are undergoing modification.

Wheelchair Usage Monitor

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Sponsor: Veterans Administration

Progress — Actual work has been in progress for six months. At this point, the basic device has been fabricated and completed, including the internal software to record and store the data. In addition, the interface device that would transmit this data to an appropriately configured computer for further analysis and storage has been completed.

The only remaining item to be completed for this project is the development of an appropriate acceleration sensor that is compatible to the device and the basic objectives of the project, i.e., a small device that can be easily attached to any wheelchair and can accurately record usage data. It is anticipated that this work will be completed within a very short time and the devices will be ready for testing.

Alternate Transit Vehicle for the Physically Disabled Person

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Sponsor: VA Rehabilitation Research
and Development Service

Purpose — The objective of this research is to design systems and subsystems for an alternate to present powered wheelchairs.

Progress — This project began as a graduate feasibility study examining conceptual designs of a transit vehicle for physically disabled persons. It became apparent that the major obstacle to any conceptual design was the fact that the control electronics did not exist. In addition, semi-structured interviews with powered wheelchair users revealed possibilities for improvement in present wheelchair controllers. The logical direction for this project then became to examine the electronics of wheelchair control, with a goal of designing a controller that was flexible enough to serve as a retrofit item for present chairs or the more sophisticated control of future conceptual designs.

The first prototype has been constructed and is undergoing initial field-testing. The controller is microprocessor-based with optical encoder feedback and is an

original design in power processing. As a retrofit item for present powered wheelchairs, it offers several advantages in addition to a projected consumer cost that is below that of present controllers. One advantage is that costly hardware modifications which customize the controller to special needs are not needed because the design is implemented in software instead of hardware. All controller characteristics are set in software and are user/therapist programmable. The controller is silent in operation with no audible relay chatter or motor hum. Closed-loop control provides the classical advantages in addition to a path memory feature that allows the chair to automatically back out of a confined area along the same path it entered. A degree of self-diagnostics is presently functional and is presented to the user through an 8-character display. The processing power of the controller remains virtually untapped with much of the signal processing handled by support devices. This allows the controller to assume additional functions in addition to driving the wheelchair.

Future Plans — With the basic hardware design finalized, future work will be concentrated in software development. Two grant applications are currently under consideration for funding. They address the human factors considerations of wheelchair control. Control strategies to be examined include logarithmic velocity control, proportional acceleration control, deadband limits, and a variety of digital filtering techniques. Additional self-diagnostics are to be incorporated including current monitoring on each motor.

One of the most promising features of this controller is that it would solve a growing and substantial problem for powered wheelchair users: the congestion of assistive devices on their chair. Each new aid typically requires special attention to make the device accessible to each individual. The joystick or other interface used to drive the chair also can access a variety of other functions. Future plans include incorporating several devices in this manner including remote environmental control and other aids through the RS-232C interface.

Development of a Linear Synchronous Motor for Wheelchair Use

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The Linear Synchronous Motor (LSM) is a wheelchair drive system designed to take advantage of recent high tech advances in motor controls to implement a wheelchair drive system that is less expensive, more efficient, requires less maintenance, is lighter weight, and will perform with optimum efficiency at any speed on any terrain. This motor will be built into the circumference of a wheelchair wheel where the wheel becomes the rotating member of the motor, and the coils that control this rotation will be mounted onto the frame. Thus, there are no moving parts in this system but the wheel itself. It is intended that this system eventually become an integral part of an intelligent computer-controlled drive train for powered wheelchairs.

The purpose of the current contracted research is to design, build, and bench test a single LSM motor on a wheelchair wheel.

Progress — Money was received and work began on this project on April 1, 1985. During the first two months, the research team worked out a rough

mathematical model of the motor design. Based on this initial motor design, the team also designed and ordered parts for the microprocessor-based controller which will be required to drive this motor. Initial mechanical design of the motor also has been done and parts ordered. A more detailed mathematical model of the motor is being designed; however, the computer needed for this work has not been received as of this writing.

Future Plans—The system will be constructed in the mechanics lab at the Atlanta VAMC as soon as parts are received. The motor windings will be wound by the local Cleveland Electric Company. As of this writing none of the materials ordered have arrived, however most of the parts are expected within a few weeks.

After construction, initial tests will be conducted to verify the mathematical model and the feasibility of using this particular design for wheelchairs. Any problems in the design will be studied with respect to the overall design and, if possible, a redesign will occur which will attempt to remedy the problem. Then, final tests of efficiency, torque, ease of control, and reliability will be performed as best possible on a bench prototype. These results will then be compiled and evaluated with respect to the feasibility of using the LSM as a power train for powered wheelchairs.

Manual Wheelchair with Anti-Rollback Wheel

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Sponsor: VA Rehabilitaton Research and Development Service

Purpose—The manual wheelchair with anti-rollback is a completed project which involves the design of an anti-rollback wheel for manual wheelchairs. The system is transparent to the user, i.e., it is controlled entirely through natural movements in using the wheelchair.

Progress—Two patents have been granted on the initial and advanced designs of the system as previously reported.

Future Plans—As efforts develop to establish a national center for evaluation and testing, this work can proceed. Until national guidelines have been established and funds made available for evaluation and testing, the final phase of field evaluation cannot be completed.

University of Virginia Rehabilitation Engineering Center

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Sponsor: National Institute of Handicapped Research

Purpose—The Rehabilitation Engineering Center is in the third year of a five year program, conducting research on wheelchairs and seating for the disabled. Some of the seating studies are contracted to the University of Tennessee Rehabilitation Engineering Center at Memphis.

The emphasis at the Rehabilitaton Engineering Center is to conduct technical studies on all aspects of wheelchair and seating design and function that will lead to a better understanding of the principles involved and hence contribute to improved design, fabrication, and prescription.

Progress — Recent work on specific tasks includes:

1) A study on the effects of mechanical advantage on propulsion efficiency with handrims has been completed. Typically, efficiency increases if the handrim is geared to rotate at about half the speed of the wheels;

2) A study on the effects of seat position on propulsion performance has indicated that there is little effect for levers within the range studied, but seat position is an important factor when using handrims. Better results are obtained with the seat moved further back than normal;

3) EMG activity has been studied with various seat positions using lever propulsion. The muscles used are highly dependent on seat position;

4) The effects of lateral slope on wheelchair performance has been studied on the treadmill and an analytical formula developed indicating double the effort for a two-degree slope;

5) A method for recording seat and back contours has been developed and implemented. Information on these contours has been integrated with pressure data and will be used to determine appropriate cushion shapes for modular seating;

6) The effect of hip position on tone and function has been studied using EMG activity. Subjects for the study have been children and young adults with cerebral palsy and data analysis focuses on muscle tone and upper extremity function;

7) Anthropometric data of persons with disabilities have been collected routinely at the seating clinic at Charlottesville and Memphis. In addition, optimum seating configuration for these persons has been recorded based on clinical judgment. When analyzed, the information will be useful for seating design;

8) A survey has been made of various fitting and measuring techniques and a uniform terminology developed. Adjustable fitting seats have been constructed for clinical use;

9) Caster shimmy studies have continued to determine the effect of friction and viscous damping and the effect of tilting the caster axis;

10) Three commercially available sprung forks have been examined to determine their natural frequencies and the effect on rider comfort and frame stresses;

11) Stress analysis of wheelchair frames has been continued. Points of maximum stress have been identified for three wheelchairs and verified with strain gauges. A program S/SAM™ has been demonstrated for use with personal computers;

12) Wheelchair component life spans have been examined using strain gauge measurements. The effect of four different caster forks was studied showing that the reduction in natural frequency can result in increased fatigue life;

13) The problem of directional instability associated with rear caster wheelchairs has been examined and an analysis of the destabilizing moment developed;

14) Dynamic brakes for manual wheelchairs have been examined and a survey of owner needs conducted in cooperation with the Paralyzed Veterans of America indicating two-thirds of the respondents desire such brakes;

15) Seven different materials have been tested to determine their suitability for non-pneumatic tires to decrease rolling resistance. The hysteresis loss factor is a major contributor to rolling resistance;

16) A choke coil has been designed and tested to improve electric motor efficiency when controlled with pulse width modulators. Improvements of up to 39 percent were observed for indoor use. Noise is also reduced;

17) The water loss problem in NICAD batteries has been examined. Starved electrolyte and gel type lead acid batteries are being tested;

18) A battery monitor that keeps a log of current flow during charging and discharging and estimates the percent capacity, based on this and open circuit voltage, has been designed and is under test;

19) An adaptive controller for wheelchairs to provide optimum time response to velocity commands for varying load conditions is under development. The velocity response is excellent but problems remain in switching to each of the four possible modes;

20) Considerable work has been done with respect to wheelchair standards for ANSI and ISO including rolling resistance, the coefficient of friction, seating dimensions, fatigue testing, and impact testing;

21) Wheelchair product design has included modifications to the NASA-UVA composite wheelchair, a simplified version of the lever drive system, a body steering concept, and the first prototype of a wheelchair utilizing the Balans seating posture.

Seating Systems for Body Support and Prevention of Tissue Trauma

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The goal of this project is to investigate the factors that influence the development of pressure sores and postural deformities in the seated spinal cord injured individual and to develop seating system components that help to reduce the incidence of such problems. Present efforts are testing of seat cushion and postural trunk supports (low back) on sitting balance, upper extremity function and objective interface sitting pressures. In our initial work with low back support, interface pressure measurements show drop of 5 mm Hg under the ischial tuberosities in 23/26 patients. While these data are preliminary, they have clinical significance to prevent tissue trauma on the ischial tuberosities.

A study has been initiated to investigate how various thicknesses, shapes, and sizes of low back cushions influence pressure distribution, trunk balance, and user comfort. These data will be analyzed to develop low back cushion specifications and guidelines for prescription.

Maintenance Free Battery

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Sponsor: VA Rehabilitation Research and Development Service

Progress — A good deal of equipment in use at this hospital, including patient movers and wheelchairs depend upon batteries as the power source. Thus, the type of battery used is critical to the performance of the equipment. Although the manufacturers of wheelchairs specify that DEEP CYCLE batteries be used, it appears to be standard practice that automotive batteries are used. DEEP CYCLE

batteries are built with fewer, but heavier lead plates made of a more dense material and are designed to deliver lower currents continuously for many hours resulting in greater range and power. The denser lead plate material is capable of withstanding as many as six times the number of discharge-recharge cycles as an automotive battery. The YUASA NP battery was recently introduced in the market. This battery is air transportable and embodies all of the positive features of DC batteries and is also maintenance free. Because of its unique electrolyte suspension system, this battery can be used in any position without loss of capacity electrolyte or service life.

To obtain maximum efficiency and long life of batteries, simple guidelines should be followed: 1) determine correct battery size and type; 2) utilize the proper charging equipment; 3) proper maintenance helps eliminate premature battery failure. An ideal battery for a 24 volt system (2-12 volt batteries) wheelchair would be a battery that is lightweight, compact, sealed/maintenance free, air transportable, low self-discharge rate—extended shelf life, operational in any position, capable to meet performance requirements as set forth by manufacturers of wheelchairs.

A battery that meets these specifications is a YUASA maintenance-free rechargeable battery. The cost of a YUASA battery (purchased in lots of 50) that would be suitable as a replacement for the now used 22NF series is $57.97. Purchasing larger quantities would reduce this cost considerably. The use of DEEP CYCLE batteries and appropriate battery chargers would be cost-effective and result in more satisfactory wheelchair performance.

New Designs for Personal Lifts

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Many wheelchair users need help transferring in and out of their wheelchair. Sometimes all they need is help from another person. But often a hydraulic or electric lift is required. These lifts are heavy and cumbersome, and a nuisance to transport when traveling.

Progress — Our "PROTEUS Lift Chair" makes life easier for people who need lifts for wheelchair transfers. PROTEUS combines the functions of a powered wheelchair and a hydraulic lift into one, compact unit. We redesigned the chassis of a powered wheelchair to provide a socket that can hold a detachable hydraulic lift. A person can be transferred from the wheelchair by placing him/her on a sling, attaching the lift to the sling and hoisting him/her clear of the wheelchair seat. Once the person is clear of the wheelchair seat, it can be swung out of the way, and he/she can be moved into the desired position and lowered into place.

When the lift is not needed, it can be easily removed and PROTEUS becomes a standard powered wheelchair that can be used either indoors or outdoors. Since PROTEUS chassis has a shorter wheelbase than most other powered wheelchairs, it is also very maneuverable.

A working prototype of PROTEUS is now available for evaluation, and we also have been in contact with wheelchair manufacturers regarding future plans for manufacturing it.

Mapping the Buttock-Cushion Interface Contour with Ultrasound: Significance in Seating for Pressure Sore Prevention

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose — Clinical problems associated with the management of patients susceptible to pressure sores present a major challenge for the rehabilitation team. Spinal cord injured persons are at a particularly high risk for tissue breakdown. Methods for prevention of pressure sores includes first identifying areas of high pressure between the body and support surface and then selecting or fabricating a cushion that will redistribute forces over a larger surface area and thereby reduce pressure peaks and gradients. However, the capacity to distribute the pressure uniformly at the support interface does not depend only on cushion properties; rather it is clear that body build, weight, height, size and shape of bony prominences, and tissue resiliency are some of the factors that govern pressure distribution at the buttock cushion interface. An indirect measure of the latter may be obtained from the indentation contour of the buttock cushion interface. Data on interface contour have not been available till recently.

In the present study, a technique for mapping the three-dimensional contours of buttock-cushion interface and pressure has been proposed. The three-dimensional contour of buttock-cushion interface will be accomplished using an ultrasonic dimension gauge mounted on an X-Y positioning system. Pressure contour will be measured using a TIRR pressure evaluation pad. Measurements will be made on normal, quadriplegic, and paraplegic subjects, and differences in seating pattern will be described quantitatively for the first time.

Progress — A special chair has been designed and fabricated using 2 cm diameter stainless steel tubing. The back, arm, and footrests are similar to those on a standard wheelchair. The seat is replaced by a 2 cm thick plexiglass sheet with a 30 cm × 30 cm hole cut in the center. A thin sheet of plexiglass placed over the square hole forms the support surface for the gel cushion. The dimensions of the PVC gel cushion to be used in this study are 40 cm × 40 cm × 3 cm.

The positioning of the ultrasonic transducer is accomplished by two precision orthogonal sliding assemblies driven by high resolution stepper motors (0.9 degrees per step) under the control of an IBM CS9000 instrumentation computer. The positioning system is housed in an enclosure. In order to achieve good coupling and friction-free sliding between the ultrasonic transducer and the thin plexiglass plate, an enclosed water coupling system has been designed and fabricated. The coupling system includes a cylindrical cup for housing the transducer. An O-ring attached to the top surface of the cup facilitates smooth motion of the cup across the bottom surface of the thin plexiglass plate. A water tight seal is maintained by a spring loaded mechanism which gently presses the cup against the plexiglass plate. During data acquisition, the cup is filled with degassed, distilled water and connected to a reservoir under pressure.

In conjunction with the buttock-cushion contour information, pressure measurements are accomplished using a pressure evaluation pad (PEP). The PEP is an electromechanical device and contains a 12 × 12 matrix of pneumatically controlled flat contact switches enclosed in a mylar bag. The pad has been interfaced with the IBM CS9000 computer through an interfacing circuit via an analog to digital converter. At each inflation pressure, switch closures are read by

the computer and are displayed as a matrix of binary values. The sensing pad is placed between the subject and the gel pad. The pneumatic system is activated by an air pump and the pressure is monitored using a pressure gauge. By varying air pressure within the pad and recording the corresponding matrix of switch closures, it is possible to obtain the pressure contours under the buttocks and specifically under the bony prominences.

Computer software for acquiring buttock-cushion contour data has been completed. Software for acquiring pressure contours from the pressure evaluation pad is also under development. Development of three-dimensional graphic display software is in progress.

It was our original intent to modify the seating system used in our earlier two-dimensional system. However, the scanning system could not be housed within the framework of the original wheelchair seating system. Therefore, a special chair was designed and fabricated from stainless steel tubing. However, the project should be completed as per our original time table.

Evaluation of Powered Wheelchairs and Their Steering Systems

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — As a follow-up to an earlier project in which a method of power steering was developed for certain types of powered wheelchairs, a formal evaluation of new wheelchair designs and power steering for wheelchairs is about to begin. For this evaluation, a special van-compatible wheelchair manufactured by Mobility Engineering, Inc., a high-performance conversion of an Everest and Jennings (E&J) Model 3P chair and a standard E&J Model 3P are being equipped with power steering. The special types of chairs will be compared with the standard E&J Model 3P, and the advantages and disadvantages of power steering on each type of chair will be determined. The hypothesis is that power steering will provide improved stability on laterally sloping surfaces and over rough or hilly terrain.

Progress — The wheelchairs will first be given an engineering evaluation to test them in all conditions under which they are expected to operate. Then, fifteen veterans and others who regularly use powered wheelchairs will be selected as participants. Each participant will test each of the three wheelchairs for one week, using it in all of his or her daily activities. Based on comments from the users and observations by the evaluation team, the wheelchairs will be modified and improved to the extent feasible, after which the same participants will test each of the chairs for another week. Prior to and following each evaluation period, each participant will be required to operate each chair through a prescribed sequence of maneuvers and conditions to provide additional objective and subjective data.

Safety problems with the power steering were encountered in the initial attempt to begin the evaluation. These problems have been corrected and installation of the modified power steering system on the E&J chairs is complete. Installation of power steering on the van-compatible chair is underway, along with an effort to recruit a suitable technician to carry out the evaluation.

A Heelstrap Retractor and a Shock Absorbing Seat Suspension System for Wheelchairs

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The heelstrap on many unpowered wheelchairs can lead to situations that are both troublesome and hazardous. In order to alight from the wheelchair, the user must position the foot pedals vertically. This can be done only if the heelstraps are forcefully pushed toward the front of the foot pedal. If this is not done, the heelstrap prevents vertical positioning of the foot pedal. The foot pedal then presents an obstacle that could trip the user as he alights from the chair.

The heelstrap retractor solves this problem by forcing the heelstrap to the proper position as the foot pedal is raised. This is accomplished with an inexpensive coil spring that is easily attached to the chassis of the wheelchair. A thin metal finger at the end of the coil spring contacts the heelstrap. Raising the foot pedal causes the finger to rotate, pushing the heelstrap forward and out of the way. This eliminates potential hazards and makes it easier to vertically position the foot pedal.

Road shocks and vibrations pose a crucial problem to users of unpowered wheelchairs. The severity of this problem can range from an annoyance to aggravation of pressure sores (decubiti). Many suspension systems have been posed to minimize the problem, but they require extensive modification of the wheelchair. Manufacturers are reluctant to adopt such designs.

Our design does not require such modifications to the wheelchair. Rather than adding suspension to the chassis, as in previous designs, we have suspended the seat. This suspension system is accomplished with spring-loaded, post-shock absorbers located between the upper and lower parts of the wheelchair chassis. A shock absorber is located near each corner of the seat. The shock absorbers dampen vibrations to the lower frame.

H. Personal Licensed Vehicles

[See also pg. 161]

A Driving Simulator for the Physically Disabled Person

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The Driver Simulator is a system designed to facilitate therapeutic evaluation of the hardware to be retrofitted to a disabled driver's vehicle. It consists of a full-scale mock-up of the necessary portion of a van interior including steering wheel, dashboard, seat, and other items necessary for driving. In front of this dashboard is a large screen monitor driven by a modified Apple IIe microcomputer on which the simulation takes place. This system is so designed to allow easy changing of hardware configurations and thus allow an individual to be evaluated for many different retrofit systems.

Progress — In September 1983, the initial design for the Driver Simulator was completed. A summary report was written and the engineering drawings were

prepared. Space for the construction of the project was arranged but no construction has started due to shipping delays in the arrival of the components. The software for this system is still under development.

Future Plans — The system will be constructed in the mechanics lab at the Atlanta VAMC. Materials for the frame have arrived and the remainder of the parts can be purchased locally. The system also may be used as a test bed for development of new driving aids for physically disabled persons.

Adaptive Systems for Disabled Ultralight Pilots

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Progress — Prototype braking, steering, seating, and positioning systems for the disabled Ultralight pilot have been designed, fabricated, and test flown.

In addition to the original designer of the Ascender Ultralight, three commercial firms have agreed to work with this project to make commercially available systems suitable for use by the disabled pilot. A pre-production fiberglass/kevlar adjustable seat system is being manufactured in Dallas, Texas by a firm expert in the use of lightweight composit construction. A safety harness manufacturer who participated in design revisions of pre-production seating/positioning prototype has agreed to produce the pre-production harness system for seating attachment as well as the safety harness for pilot crash protection. A leading manufacturer of ballistic parachute systems has agreed to make design changes (which may be required for disabled pilots) available commercially.

In transferring into the Ultralight, the fuselage tubes of the aircraft being used are 28 inches off the ground and 14 inches wide. For the severely disabled individual this presents serious problems in transferring into the aircraft. The seating and positioning system has therefore been designed to facilitate the transfer using a level transfer and sliding board. In this way, it is possible for a spinal cord injured C5/6 quadriplegic to transfer into the aircraft with one helper.

Seating and positioning is vitally important for safe functioning in an Ultralight aircraft in turbulent air conditions. For many pilots positioning is of critical importance for safe operation of the controls. Any movement of the body away from the ideal control position could potentially cause loss of control. This part of the project has absorbed most of the effort to date. For the initial part of the project, including flight tests, a boat seat was modified to fit into the Ultralight. Additional back support was added as was head support, which was quickly discarded as unnecessary and a source of vibration. The seat requires firm anchorage for positive and negative G forces as well as significant adjustability fore and aft, height adjustment, and tilt adjustment. (All seat mounting straps and safety harnesses will be manufactured to safety specifications of 2400 pounds-force per strap). In order to provide negative G for security, a cage has been constructed passing directly under the seat and providing extra protection for the legs in the case of a crash landing that causes the front gear to collapse. For leg and foot positioning, a simple adjustable calf platform provides a secure/safe positioning system.

The system has been shown to have sufficient adjustment to fit able-bodied people from 4 foot 11 inches tall, weighing 110 pounds to a 6 foot 4 inches tall, 230 pound, C6 quadriplegic. Following this initial work, a re-design has been done on the seating system and a pre-production lightweight fiberglass/keflar adjustable seating system is being manufactured in Dallas. The manufacturer of this pre-production prototype is interested in producing the seats as part of a commercialization program.

Modification to the ballistic parachute triggering system has yet to be carried out but will be relatively simple and will be readily incorporated into the production model by the manufacturers who have agreed to this in principle.

The system has not been ordered because the weight of the system will put the Ultralight well over the legal limit. In order to tackle this problem, a presentaton has been made at an FAA public meeting on Ultralight legislation arguing for a weight allowance and other devices to give equal safety to disabled Ultralight pilots. A formal petition to change FAR-103 will be lodged in due course.

The Unistik Vehicle Controller: A Unique Approach to Driving for Severely Handicapped Individuals

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Functional motor vehicle control for tetraplegics above the C6 level or people with only one functioning extremity has heretofore been only very limitedly feasible, difficult to obtain, and exceedingly costly.

Progress — The Unistik Vehicle Controller (UVC) was developed by Johnson Engineering Corporation in conjunction with and supported by the National Aeronautics and Space Administration and the VA. It consists of: 1) the driver interface, a complex joystick mechanism which converts the driver's control movements into electronic signals; 2) the signal controller, which processes and modifies the signals from the driver interface and sends them to the vehicle interface; 3) the vehicle interface, electromechanical actuators which move and position the steering shaft, brake pedal, and accelerator pedal in response to the electronic control signals; and 4) a self-diagnosis and monitoring system to warn the driver of malfunction and activate redundant mechanisms.

Characteristics of the joystick control including sensitivity, centering, feedback, or other qualities may be modified by altering software in the signal controller, thus providing reversible adaptation to individual patient needs. The UVC system is easy to control with one hand, lightweight, safe, reliable, easy to install, and can be adapted to a wide range of disabilities. Ongoing development in process includes secondary controls, reliability and safety testing, refinement of monitoring system, and adaptation of driver interface for a wide range of disabilities. The UVC is a unique system that represents a potentially highly functional and cost-effective solution to the problem of vehicle control for severely handicapped persons.

I. Functional Electrical Stimulation

1. General

External Control of the Neuromuscular System

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Sponsor: American Paralysis Association

Purpose — The application of electrical stimulation toward restoration of lost movement due to stroke and spinal cord trauma is investigated in a systematic approach. Although primitive type of muscle contraction is possible even with simple transcutaneous stimulation of the motor point, an accurate and well-coordinated movement of an extremity joint requires complex control of several physiological processes such as action potential rates, motor unit recruitment, synergy of antagonistic muscle pair and proprioceptive, and tactile and kinesthetic feedbacks.

Progress — The technique developed utilizes dual electrode assembly placed on the muscle nerve; one controls the action potential rate with pulses of low frequencies (20-60 pps) and the second electrode controls recruitment of motor units according to their size with high-frequency pulses. The other physiological elements associated with joint control are incorporated in the overall system design.

Recent studies in the laboratory established the recruitment model of the muscle, the optimal gain and model of the proprioceptive/reflexive feedback required, and the combined time and frequency response of the models.

More recent studies focused on using the myoelectric signal of the electrically stimulated muscle as the proprioceptive/reflexive feedback mode. A sophisticated recording and filtering technique was developed to eliminate artifacts from the dual stimuli, and a signal processing employing EMG instantaneous median frequency and RMS value successfully correlated the signal to the muscle force profile.

Neuroaugmentive Procedures for Modification of Abnormal Motor Control in Patients with Spinal Cord Injury

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Purpose — Sixty patients with muscle hypertonia after spinal cord injury have undergone spinal cord stimulation (SCS). These patients had spinal cord injuries (SCI) ranging from C2 to T12. Electrodes were placed above, below, or above and below the lesion in the posterior epidural space for a period of at least 3 days during which time stimulation pulses, typically of 3 to 5 MA amplitude and of 0.2 MS duration at 30 Hz were applied. The effects of SCS were monitored by recording motor unit activity with surface electrodes over leg muscles during an examination of segmental and suprasegmental spinal cord activity, in addition to patient reports and neurological evaluations. The results of spinal cord stimulation can be divided in four distinct categories. In Group I, consisting of 17 patients, or

28 percent of the entire group, the effect was characterized by marked suppression of muscle hypertonia and so-called spontaneous spasms. In Group II, the effect of spinal cord stimulation on muscle hypertonia was moderate as evidenced by the suppression of the tonic but not phasic features of spasticity. This was observed in 20 patients, or 33 percent of the total. In Group III, neurological and neurophysiological evaluations revealed only a marginal effect. The condition of this group of nine patients (15 percent) did not improve significantly. In Group IV, consisting of 14 patients (23 percent), there was no effect.

Preliminary Results — The above described results have led us to conclude that in patients with cervical lesions a marked effect is most likely to occur when the residual functions of ascending and descending systems are preserved. A possible mechanism contributing to SCS in this condition might be the activation of descending inhibitory segmental interneurons via the dorsal column, brainstem, and spinal loop. In patients with thoracic lesions, when the stimulus was applied above the level of the lesion, the effect was marginal in comparison with the marked effect obtained when stimulation was applied below the level of the lesion over posterior structures. These observations suggest that the underlying mechanism in this condition is the antidromic effect of spinal cord stimulation through posterior spinal cord structures.

Functional Neuromuscular Stimulation for Quadriplegic Patients

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Sponsor: Osaka Rosai Hospital

Progress — A very simple system using surface electrodes is being developed for C5 level quadriplegic patients. Our system consists of two-channel stimulators, a toggle switch, and a supplemental orthosis. Distinctive features of our system are that it is very simple and not invasive. Problems of this system are difficulty of placing electrodes and need of supplemental orthosis. Presently, we are preparing to develop an implanted system for these patients.

Neurophysiological Assessment of Changes Induced by Neuromuscular Electrical Stimulation in Stabilized SCI Patients

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Purpose — A number of centers in the United States and Europe have been working on the problems of electrical stimulation for the completely paralyzed spinal cord injured (SCI) patient for over 15 years. Much research and development remains to be done before a system for completely paralyzed SCI patients will be practical. Partially paralyzed patients however, can benefit now from neuromuscular electrical stimulation (NMS) for muscle strengthening and suppression of muscle hypertonia (spasticity), and from functional electrical stimulation (FES) for augmenting partially preserved movement.

At The Institute for Rehabilitation and Research in Houston, Texas, a center for clinical use and evaluation of the effects of FES has been organized as a part of the Program for Restorative Neurology. A recent study of a group of five stabilized SCI patients who used NMS and FES daily for six months found a reduction in spasticity, improved volitional muscle activity, better walking patterns, and increased gait endurance compared to their prestimulation state.

The nature and extent of changes in neurocontrol mechanisms induced by extensive use of NMS and FES in ambulatory SCI patients have not yet been described or documented. Thus, the goals of the program are to study the effects of the use of NMS and FES in partially paralyzed patients, to describe criteria for selecting patients and to examine the underlying mechanisms which are responsible for long-term stimulation effects.

The proposed research, to be conducted over a three-year period, will be carried out on approximately 10 SCI patients per year. It will include those who have the ability to stand and take a few steps. Patients selected will be between the ages of 18 and 55, with good general health and cardiorespiratory function. They must have completed a physical therapy program prior to the study.

Evaluation of the patients will be by interviews, patient questionnaires, staff observations, physical therapy evaluation, clinical neurological evaluation and clinical neurophysiological evaluation. The clinical neurophysiological evaluation will include the assessment of muscle hypertonia by an isokinetic dynamometer, assessment of segmental phasic and tonic stretch reflexes, cutaneo-muscular reflexes, long loop reflexes and postural and equilibrium control, and gait studies employing simultaneous recording of muscle activity, joint movement and studies of foot floor contact. A program of NMS or FES will be tailored according to each patient's particular needs. Stimulation goals include reduction in spasticity, muscle strengthening for both voluntary and stimulated movements, increased range of motion, standing, walking, improved patterns of gait, and improved endurance in walking.

Progress — In each patient the program will start with NMS in order to suppress spasticity in certain muscle groups and to thereby achieve initial mobilization goals and to modify existing gait patterns. As the patient becomes competent in the use of the equipment (application of the electrodes and adjustment of the stimulus strength), FES will be added to the ongoing NMS program when further improvement of gait can be achieved. At intervals of one month, functional changes in walking will be assessed. At three-month intervals, a full assessment will be made by repeating the initial battery of clinical and clinical neurophysiological tests. Patients who have shown beneficial changes at that time will then be tested over a period of up to four weeks for the persistence of these neurocontrol patterns after withdrawal of the stimulation. Following completion of the six-month-testing period, patients will be placed into the ordinary clinical routine with the addition of annual follow-up evaluations.

Responses to questionnaires and other usage factors will be assessed to determine the perceived level of utility of the stimulators. Measurement of gait patterns and quantification of hypertonicity will serve as confirmation of beneficial changes. Of great importance will be the correlation between the effects achieved and the category of the patient according to the level, severity and

extent of his spinal cord injury, i.e., the degree of neurocontrol. This comparison will serve as a basis for the development of clinical neurophysiological criteria which can be applied in the selection of appropriate SCI candidates for FES.

Influence of Continuous Electrical Stimulation on the Spinal Cord Motor Neurons

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Sponsor: Paralyzed Veterans of America, Vaughan Chapter

Purpose — Applied electric fields have been reported to facilitate regeneration or regrowth of injured peripheral nerves and severed spinal cord axons. We are conducting this study to evaluate what stimulation parameters might be best.

Progress — For the study we anesthetized female Wistar rats, 200 to 250 grams in weight, with a 6 percent chloral hydrate, then performed laminectomies to expose T10-T13 levels of the spinal cord. We inserted tantalum electrodes into the cords at a depth of 1mm and spaced 2cm apart with the current traveling in a head-to-foot direction. The stimulator was sutured subcutaneously. For stimulation we used monophasic pulses of 130 mV, 0.3 msec duration and 120 msec apart. After three months of continuous stimulation, we sacrificed all animals by perfusion with Karnovsky's fixative, then removed the spinal cords, cut them into small pieces, and processed them for the electron microscopic examination.

After three months of continuous electrical stimulation, the animals did not exhibit any motor deficits upon gross observation; they appeared normal in all respects. However, when they were allowed to walk on a smooth surface, like X-ray film, their hind limbs showed a slight deficit in grabbing as compared to non-stimulated animals. We also noted some tissue disruption of the spinal cord at the site of anodal electrode insertion. Our electron microscopic examination of motor neurons located between the two electrodes and below the cathode showed typical-appearing neurons, glia, and synaptic structures. However, upon further observation, we noted an alteration in the stacking of individual strands of rough endoplasmic reticulum and the distribution and quantity of Nissl substance of the motor neurons.

Computer-Controlled 22-Channel Neural Stimulator for Functional Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — It has been possible to modify the NUCLEUS Multi-Channel Implantable Hearing Prosthesis (Nucleus Ltd., Lane Cove, Sydney, Australia) into an implantable 22-channel neural stimulator for use in functional neural stimulation (FNS). This is being designed to be used for patients with upper motor neuron lesions following spinal cord injury or stroke. A new computer software program was developed by Dr. Richard Eckhouse of MoCo Inc. for use with a desk top microcomputer that was connected to the speech processor interface (SPI). The SPI in turn activates the external antenna which overlies an implantable receiver-stimulator (RS). The RS module was modified by deleting the cochlear lead electrode and substituting 22 individual insulated wires leading to a D connector for our laboratory use in animals in our initial pilot study.

Progress—The pilot study undertaken in 1985 has shown that this 22-channel stimulator can be controlled by the computer program to activate peripheral nerves in the leg of anesthetized rabbits so that the muscles can be fully controlled and contracted to move the joints of the lower extremity. The software program was able to activate single or many electrodes so that a single muscle could be activated independently or that a group of muscles could be activated causing co-contraction at a joint such as the ankle or simultaneous movements of the joints of both legs at the same time. A program has been started allowing data to be collected from human peripheral nerves at the time of amputation. The parameters of stimulation producing maximal contraction of leg muscles are well within the power output of the stimulator (maximum 2.3 mA, 400 msec, 20-50 Hz).

Future Plans—The pilot project for 1986 is in two parts: 1) To continue building up data from the stimulation of human nerves at surgery (such as amputation, vascular and hip prosthesis). The choice of electrodes and their testing also will be carried out during the acute surgery. The constancy of the radio stimulator also is being checked weekly for its power output under various temperature changes; 2) Dr. Richard Eckhouse (MoCo Inc.) with the cooperation of Nucleus Ltd. is undertaking a design and construction of a belt-worn microcomputer containing software programs capable of producing patterns of exercising, standing, walking, and stepping in patients with paraplegia and stroke.

Functional Electrical Stimulation

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Sponsor: Regency Park Centre for Young Disabled

Purpose—Denervated or partially innervated muscles can be electrically stimulated into action. This exciting new technique requires further investigation regarding its value in retraining muscle action following spinal cord injury, and in regard to its orthotic application.

Our aim is to introduce functional electrical stimulation (FES) into our treatment programs in a controlled manner in which physiological and functional benefits are monitored.

Progress—The effects of functional electrical stimulation will be studied in two areas:

1) *Upper Extremity Muscle Strengthening of Spinal Cord Injured People.* In the preliminary phase, we will purchase two FES units (left and right), a myometer, and will fabricate feedback orthoses for elbow and wrist. We also will purchase a computer and develop software for display feedback of wrist and elbow flexion and recording of results.

In the experimental phase, approximately six subjects will be studied over a 12-month period. The experimental design will consist of alternative three-to-four month periods of FES assisted exercise and isotonic exercise, with concurrent weekly measurements of strength and range of motion by a second therapist who will be unaware of the subject's muscle strengthening regime.

In the concluding phase, we will publish results in a professional scientific journal and, if the technique is successful, introduce it into regular treatment programs.

2) *Orthotic Gait Assist Applications*. In the preliminary phase, we acquired components, designed and fabricated a 2-footswitch 2-channel stimulator suitable for applications in gait training.

In the experimental phase, the application of functional electrical stimulation to dorsiflex and evert the feet of ambulant cerebral palsied children has been described, and we will compare this form of orthotic application with conventional orthoses with particular regard to any carry-over effects.

In the concluding phase, we will publish results in a professional scientific journal and, if the technique is found to be successful, introduce it into regular treatment programs.

EMG as Force-Feedback in Closed-Loop Functional Electrical Stimulation

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Purpose — While a number of experimental functional neuromuscular stimulation (FNS) systems have been reported to restore locomotor function to paraplegics and grasping to quadriplegics, few if any FES devices exist that patients will accept in daily living; none are commercially available and clinically prescribed. Our objective is to develop a closed-loop FNS system to improve dynamic force and position control which in turn would increase patient acceptance. Feedback control of movements should increase repeatability, reliability, and smoothness of responses; reduce mental and physical effort; and facilitate coordinated control of agonist and antagonist muscles of several joints.

Progress — Our approach is to provide muscle force feedback by extracting from the stimulated EMG response information related to muscle force and metabolic state. Nerve cuff stimulating and intramuscular stimulating and/or recording electrodes will be used. Stimulus artifact will be examined and techniques for separating it from force information determined. The shape and variability of the EMG response and its dependence on electrode parameters, particularly orientation, will be analyzed. Computational techniques for transforming the EMG signal into force output will be evaluated. An FNS controller will be implemented using force and position feedback to achieve dynamic reciprocal control of the gastrocnemius and tibialis anterior muscles of the cat ankle joint.

EMG and force data have been collected from several rats and one cat. We are using a WPI Iso-III optically isolated stimulus unit capable of converting an arbitrary biphasic signal into constant current output. When stimulating and recording from separate 7-stranded stainless steel teflon coated intramuscular electrodes (Medwire #316SS 7/44T), computer controlled monophasic stimulus pulses (50-100 us width, .05 ua to 10 ma) resulted in minimal stimulus artifact which typically disappeared within 1 ms following the stimulus. Polarization of the stimulus electrodes lasted tens of ms. Thus, contamination of the EMG can be prevented by delaying EMG sampling by 1 ms. This is acceptable since the primary EMG waveform during intramuscular stimulation occurs between 1 and 3 ms following the stimulus onset. (Force onset began about 10 ms after stimulus onset and lasted until 50 to 100 ms).

It has been found necessary to digitize EMG data at 10 khz and force at 1 khz, for which special data acquisition routines have been written. These routines allow trains of pulses of varying interval, width, and amplitude to be applied to a single muscle. EMG responses show considerable variation in shape. They may be bi-or triphasic, and in some cases change from bi- to triphasic as a function of increasing amplitude, presumably due to recruitment of additional motor units. We are in the process of systematically investigating these changes as a function of stimulating and recording electrode orientation and location.

We are also in the process of building a restraining table for the cat hindlimb with which the ankle joint can be manipulated and ankle forces measured.

I. Functional Electrical Stimulation

2. Upper Limb Applications

Implantable Systems for Stimulation of Skeletal Muscle (Guinea Pigs, Dogs)

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Sponsor: National Institutes of Health

Purpose — The objective of this project is to develop an implantable stimulator system for electrical excitation of paralyzed skeletal muscle. This system will be utilized by high level (C5 and C6) spinal cord injury patients to provide controlled grasp and release in the hand. In this application functional neuromuscular stimulation has previously been demonstrated to be effective by employing chronically indwelling percutaneous electrodes. Through the use of the implantable system, we expect that the ease of use of the system and its reliability will be improved, leading to greater independence for the quadriplegic patient.

Progress — The objective of development of the implantable system will be met by: 1) development of circuitry using a high density of integration to perform the stimulation function; 2) development of techniques for encapsulation of the stimulator in a hermetic package suitable for extended periods of implantation (greater than 5 years); 3) development of stimulation electrodes and lead wire interconnections which are suitable for use with the implantable stimulator; 4) development of a programmable control transmitter which is worn externally by the subject and regulates the output of the implant stimulator in response to the control signals generated by the subject; and 5) evaluation of the entire system and individual subsystems (e.g. electrodes, packaging) *in vitro* and *in vivo*, and modification of the design where necessary. The principal applicaton of this study is the upper extremity in the quadriplegic subject. However, the technology being developed in this project is expected to be directly applicable to other neurological deficits, such as stroke and cerebral palsy, thus enabling researchers and clinicians to have a powerful new technique more available for rehabilitation of motor function.

Myoelectric Controller for Orthotic/Prosthetic Systems (Cats)

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Sponsor: National Institutes of Health

Purpose — The aim of this project is to develop the techniques and instrumentation necessary for the high spinal cord injury and amputee population to obtain multiple command control signals for use in activation of upper extremity orthotic and prosthetic appliances. Emphasis is placed on producing command signals that are proportional in nature and with sufficiently high signal-to-noise ratios for the execution of finely controlled movements. As a result of this research, we will develop a command control scheme which optimizes the performance and fidelity of the output device.

Progress — The performance of this control scheme will be demonstrated in an animal model. Specifically, this project will produce a complete myoelectric controller system. This system will consist of two major subsystems: 1) an implantable intramuscular electrode array linked to a multichannel telemetry device; and 2) a telemetry receiver/myoprocessor. The latter subsystem will be a compact microprocessor-based unit that can be incorporated into a portable functional electrical stimulation system or powered prosthesis. The telemetry device will be available in two optional packaging configurations: a self-contained RF-powered telemetry device or a telemetry device with a separate RF power module receiving antenna.

Functional Neuromuscular System for Upper Extremity Control

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The objective of this project is to develop systems for functional neuromuscular stimulation and implement and evaluate their effectiveness in providing restoration of upper extremity function in the high level spinal cord injury subject. The studies performed in the past year have focused on the development of the system hardware and software for implementation of implantable stimulator systems into human subjects. These developments are in the implantable stimulator device and in the external control unit used to regulate the implanted unit.

Progress — In the area of implanted stimulator development, circuitry modifications have been designed into our implantable device which will provide for five bit regulation of current amplitude. This amplitude regulation is in addition to the pulse width control (1 usec resolution over a range of 0 to 255 usec) and interpulse interval control (1 msec resolution from 0 to 50 Hz) that has previously been available. Integration of this circuitry on a semi-custom CMOS integrated circuit is presently underway, and fabrication of final circuits are expected to be completed by January 1, 1986. Implantable stimulator units have been undergoing animal evaluation (under support of the NIH), and we expect completion of this phase of testing to be ready for human trials in the first quarter of 1986.

Development of the external control unit has undergone extensive redesign and refinement. The new hardware provides for more versatile processing of input

command control signals, generated by the user, and for regulation of the output stimulus signals. The unit is based on two CMOS microprocessors (RCA CDP 6805E3), one which performs input processing and one which modulates stimulus parameters. The device is able to control two implantable devices to their full capabilities and four implants with more limited capacity for individual control of the ipi and pw of each channel. The design of the external controller is nearly complete, with the exception of the final design of the radio frequency transmitter. The design is implemented in four interconnected circuit boards (modules). The layout of printed circuit boards is partially completed and some modules are under fabrication.

Software to perform the control and modulation functions has been updated from the present version of patient portable device. This software provides for ease of programming the control and stimulation parameters into the portable unit from the laboratory computer system. The software presently functions equivalently to the present patient portable device, but software updates will allow for additional input processing as well as monitoring of device usage and system checking, for example, of broken electrodes or low batteries.

We expect to introduce the new device into clinical usage in January, 1986, in conjunction with percutaneous electrode systems which are presently implemented with our eight clinical subjects, and subsequently with the implantable stimulator system.

I. Functional Electrical Stimulation

3. Lower Limb Applications

Weight Transfer Training Using Biofeedback and Electrical Stimulation in Strokes and Incomplete Spinal Cord Transections

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — The hypothesis is that patterned electrical stimulation of lower extremity muscles will facilitate patient awareness of the involved leg, transfer of weight to the leg, and assist therapists in teaching standing balance and weight transfer.

Progress — The method is to design and construct a weight-bearing test device, weight transfer apparatus, force feedback display, and electrical stimulators. Study and control groups will be observed to determine if weight-bearing, gait, endurance, energy expenditure, and ambulation level are altered by patterned electrical stimulation.

The goals are to improve a gait training program for patients recovering from certain neurological conditions, shortening hospitalization time, and providing an improved level of ambulation.

Electrical Stimulation in Cerebral Palsy Hypotonia

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Sponsor: Louisiana Center for Cerebral Palsy

Purpose — Substantial variations of antagonist muscular development related to tone, strength, and size are extremely debilitating in the various gait cycles of cerebral palsy patients. Furthermore, during standing such muscular imbalance results in poor posture, fast fatigue, and its associated secondary implications.

Progress — A study was conducted on selected groups of hemiplegics, diplegics, and paraplegic cerebral palsy patients who are able to walk. All the patients had stronger hamstring muscle groups that resulted in gait and posture with partially flexed knees. The patients received 15 minutes of cycled electrical stimulation of the quadriceps three times a week and were tested for functional performance on the Cybex system before the stimulation program and every two weeks during the program.

Of the 12 patients, 80 percent had substantial increase in quadriceps bulk, strength, and endurance. Parents of the patients reported improved gait and fatigue resistance as well as posture. Of the remaining two patients, no substantial improvements could be recorded, even compared with controls. We suspect that psychological factors, primarily lack of motivation, prevented some patients from maximal performance during the Cybex evaluation.

Patients showing improvement after 6 to 8 weeks were removed from the stimulation therapy for 10 weeks for us to assess whether the improvement was permanent, temporary, or dependent on ongoing stimulation. Cybex evaluation is pending at the end of the 10-week intermission.

Computer Models for Designing FES Systems for Paraplegic Standing and Walking

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Purpose — Restoring motoric function to spinal cord injured persons by functional electrical stimulation (FES) of their paralyzed muscles has been explored for over 20 years. It has been demonstrated that muscles activated by FES can enable paraplegics to rise from a chair, stand, and walk. These pioneering efforts have identified major technological problems prohibiting routine clinical prescription of FES as a means for paraplegics to regain function of their legs. One of these problems is the lack of computer models both for designing FES systems to control standing and walking in paraplegics, and for determining the trade-offs among the different designs. Knowledge obtained from studying these trade-offs should reduce the amount of experimentation needed to develop clinical FES systems for restoring mobility to paraplegics.

Progress — We are developing a computer model based on modern engineering control principles that can be used to study simulated FES induced standing and walking in paraplegics. The model will include the dynamic interactions among the ground, the legs, the torso, the arms, and the static and dynamic properties of the stimulated muscles.

The computer model will be used first to study, design, and evaluate FES feedback control strategies needed to induce stable standing in paraplegics. The

performance of these FES systems will be based on both subjective and objective measures of simulated standing ability. The subjective evaluation will be based on an animated graphics display of a simulated standing paraplegic. The objective measure will be a scalar, or score, based on the FES system's ability to maintain stability and minimize muscle fatigue.

Restoration of Locomotion in SCI Patients Using FES

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Sponsor: University of Strathclyde

Progress — This program has been established in collaboration with the Departments of Electrotechnology at the Universities of Ljubljana and Belgrade. The aim is to evaluate and develop FES orthotics using, for the present, surface electrode technology. The project has so far concentrated on the development of FES aids for standing and walking. It is anticipated that the standing aid will be made commercially available in the near future. Walking aids have been used by some SCI patients, incompletely lesioned at cervical and thoracic levels, to attain independent crutch-aided ambulation. Prototype Hybrid Orthoses have been developed and are being investigated for use by SCI patients completely lesioned at thoracic levels.

Biomechanical and Physiological Evaluation of Paraplegics Activated by Functional Electrical Stimulation

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Purpose — The safe application of functional electrical stimulation (FES) for the activation of paraplegics requires objective and quantitative means to biomechanically and physiologically evaluate these patients. In this research both these aspects are being investigated: the biomechanical by means of weightbearing during standing and kinematics of the stride during reciprocal walking; and the physiological by parameters such as heart rate, pulmonary function, oxygen consumption, and blood flow.

Progress — FES is being used to generate supported gait in paraplegic patients with traumatic upper-motor-neuron-lesion, between T5 and T12 spinal levels. The quadriceps and gluteus maximus muscles are stimulated simultaneously to achieve a supported standing position, while hip, knee, and ankle flexions are achieved alternately for each leg by stimulating the shank surface at two selected locations. The stimulus used has an intensity of 90 mA, duration of 0.3 msec, and frequency of 30 Hz. Standing and walking of the patients are being monitored in the gait laboratory of the Loewenstein Hospital. The amount of weight-bearing on each foot during standing is established by time integration over a standard period of time of the reaction forces as measured by 'Kistler' force platforms on which the patient is required to stand while taking care to support his walking aids outside the platform area. Gait of the patients is evaluated by means of an electrical contact system, in which time-distance parameters of the stride are being measured. Computer processing of the data acquired is used to obtain objective evaluation of the patients' progress during their training period.

The influence on the cardiopulmonary system of muscular contractions of the paralyzed limbs in paraplegia activated by FES during treatment and the energy cost of standing and walking while using FES as an orthotic aid also are being evaluated. At the end of a training program, heart rate and oxygen consumption of the patients are monitored as follows: at rest; following 30 minutes of FES in the sitting position; following 15 minutes of standing; and during ambulation. Lactic acid level during maximal effort are taken as well.

Preliminary Results — A training method for the activation of the lower limb muscles of paraplegics by functional electrical stimulation (FES) for standing and walking was developed. It consists of a daily program that does not interfere with the normal routine of the patient. The treatment of seven patients, paralyzed from 4 to 30 years and with ages from 26 to 50 years, was applied. In these patients, a good standing position was achieved by stimulating the quadriceps, sometimes supplemented by the gluteus maximus or medius muscles. Gait was obtained by activation of the flexion reflex in a single stimulation and by tilting the trunk. Difficulties during gait were encountered due to the strong adduction of the legs. No mechanical support was required for locking of the lower limb joints. However, to maintain the equilibrium of the body, external support such as parallel bars, walker, or Canadian crutches were used. During treatment, gait improved due to reduction of spasticity and better stability of the body. Biomechanical measurements of weightbearing on the legs indicated values ranging between 41 to 65 percent of the body weight. During gait, a steady improvement of velocity was noted, with a parallel decrease in stance and stride times.

The physiological results indicated a low energy cost of FES in the sitting position and during usage of FES as an orthotic device for standing, confirming the beneficial effect of FES for spastic paraplegics. However, effort invested during ambulation by means of FES was found exhaustive.

It should be pointed out that the low weightbearing on the feet could be the cause for the high energy expenditure due to the extensive involvement of the upper limbs during standing and walking. This can strongly be affected by the posture of the patient in the upright position, which in turn can be controlled either by stimulation of the gluteus muscles or by usage of a brace, both of which are now being studied.

Walking Restored in Paralyzed Man Using Electronic Orthotics

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Research activities in this program are directed toward further development of a neuromuscular orthotics system that will provide paralyzed persons with specific functional activity.

Progress — During the past year, we have addressed the specific concerns of walking speed and the use of walking aids and have begun to investigate the issues of energy expenditure, postural stability, and the ability to safely withstand sudden perturbations.

Six subjects with complete spinal cord lesions ranging from T4 to T11 and no significant peripheral nerve damage were implanted bilaterally with percutaneous intramuscular electrodes in the hip flexors, extensors and abductors, knee extensors, dorsiflexors, and plantar flexors. Stimulation patterns were developed by trial and error on the basis of normal activities of these muscles. Electrical stimulaton was provided by either a laboratory computer or a portable microprocessor-controlled stimulator. Gait patterns were evaluated using gait laboratory instrumentation for foot-floor contact and goniometers for angle measurements at the hip, knee, and ankle. Videotape records of some trials also were made. Metabolic energy requirements for electrically-assisted walking and walking with braces were compared.

Each subject had between 50 and 70 electrodes functioning at any time. Analysis of 702 electrodes implanted in the six subjects over a period of 29 months showed a probability of electrode failure which decreased exponentially during the first four months, and then continued constant at two to three percent per month thereafter. Selected failed electrodes were examined with scanning electron microscopy; failures due to manufacturing defects and to fatigue were observed.

With full quadriceps stimulation, the knee extension maximum force was 80 percent of normal while hip muscle (gluteal and hamstrings) forces remained well below normal. With practice patients progressed from using parallel bars to a rolling walker and, in one case, to axillary crutches.

Implantation of the hamstrings, gluteals, and soleus (in addition to the hip flexors, knee extensors, and dorsiflexors) allowed better posture control and improved quality and speed of the gait. Measurements carried out on one subject showed a 40 percent increase in stride length (from .7 m to 1 m), 2.5 times increase in speed of walking (from .16 m/sec to .4 m/sec, over a distance of 15 m), a decrease in time of double support (from 1.24 sec to .58 sec) and less use of the walker for support. Another subject's walking speed increased from .1 m/sec to .48 m/sec, and the stride length increased from .64 to 1.4 m.

Closed-loop control for standing was introduced in the laboratory computer system with the plantar flexors providing extension moments at the knee for small corrections of the knee and ankle angles and the quadriceps making the larger corrections. The Proportional-Integral-Derivative controllers used, one for each knee and ankle, allowed good standing quality and excellent disturbance resistance for periods of 5 to 10 minutes.

Taking account of the relative muscle masses functioning during FES walking and long-leg brace walking, we found the energy efficiency of FES walking to be comparable with that of brace walking.

Future Plans — Work is directed toward: 1) continued improvement in electrode design and implementation; 2) development of a new stimulator with a larger memory to allow programming of additional functions and to provide interpulse interval modulation of stimuli to increase the response of muscle; 3) development of adaptive controllers to obtain longer duration standing and to provide closed-loop control for walking; 4) evaluation of sensor needs and design of those necessary for the closed-loop system; and 5) development of an improved muscle model.

Sensory Nerve Stimulation for Improved Neuromuscular Control

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Progress — The influence of electrical stimulation of sensory nerve (SNS) upon motor unit control has been investigated in 17 young adult control subjects and 12 subjects with spastic lower extremity paresis. Tonic 20 Hz–0.1 m/sec stimulation of sural nerve at the ankle at levels producing non-painful paresthesias or a sense of pressure over the side of the foot was applied while subjects attempted to maintain constant minimal dorsiflexion of the foot just sufficient for activation of a single motor unit in the absence of EMG or force feedback. Most normal and abnormal subjects feel compelled to increase effort. Some lose awareness of the level of effort and stop dorsiflexion. Usually, proprioception is altered by SNS, the net effect of which is an increase in the force of dorsiflexion. In patients with spasticity, SNS decreases resistance to passive movement at the knee and ankle.

In patients with spastic para- or hemiparesis SNS can improve gait if SNS elicits a strong flexion reflex and the patient is able to stand. Peroneal sensory stimulation is more convenient than sural nerve stimulation. Stimulus intensity was adjusted to produce paresthesias but no motor response. Tonic bilateral stimulation can be used. Heel-toe walking was improved and did not require alternating stimulation of each leg. In some patients SNS was found to enhance the first inhibitory phase of the H-reflex excitability cycle at 70 m/sec. Thusfar six patients have been evaluated using peroneal sensory nerve stimulation. Each has used the stimulator daily for at least six weeks. The technique has proved to be a useful aid to ambulation.

I. Functional Electrical Stimulation

4. Other

Predictive Factors for Restrengthening Paralyzed Muscle by Electrical Stimulation

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Purpose — Electrical stimulation of paralyzed muscle could be potentially useful for many persons with spinal cord injuries, however little work has been done to document this assumption. Furthermore, electrical stimulation is not presently being used on a large scale for persons with spinal cord injuries because physicians cannot predict how various patients will respond to electrical stimulation. The goal of this project is to develop a set of tests that will help physicians to predict the responses of muscles to electrical stimulation.

Progress — We have begun preliminary studies on determining predictive factors with 18 patients of the Hines VA Spinal Cord Injury Service. All patients have given their informed consent to the research protocol. This predominantly male population provides a diverse mix in terms of level and completeness of injury,

actual age and years post-injury, height and weight, and medical and psychological complications brought on as a result of spinal injury. We have not considered individuals with damage to their spinal cord below T11, with severe peripheral vascular or cardiovascular problems or with presssure sores in areas affected by stimulation, for this protocol.

We completed initial evaluations on these patients using electomyographic, radiographic (CT scan), and neuromuscular techniques, before entering them in a 4-to-8 week protocol. In this protocol we are stimulating their thigh muscles twice daily during 20-minute exercise sessions, tracking changes in thigh muscle force and fatigue characteristics from week to week. Preliminary results suggest a possible correlation between muscle mass (as determined by CT scan) and initial response to electrical stimulation.

Spasticity Suppression with High Frequency Electrical Stimulation

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Purpose — Current procedures to alleviate spasticity in stroke, cerebral palsy, and head and spinal trauma patients consist of muscle release or neurotomy. These procedures are not reversible or of pharmaceutical intervention, which may cause overall activity suppression and addiction if long-term therapy is administered.

Progress — To circumvent such side effects, we investigated the use of high frequency electrical stimulation as a reversible means of suppressing undesired motor activity.

The studies conducted last year showed that at stimulus pulse rate of 600 or 900 per second, the lowest pulse amplitude and duration are required. Further investigations showed that induced muscle force is suppressed most likely by reversible depletion of ACh in the neuromuscular junction but not by localized nerve membrane block at the stimulus electrode site. The blockade was shown to last effectively over two hours with full reversal of force on stimulus removal.

Electrical Stimulation in Treatment of Scoliosis (Human, Cats, Sheep)

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Sponsor: National Institutes of Health

Purpose — The goal of this project is to develop a method of treating idiopathic adolescent scoliosis by effecting corrective forces through percutaneous electrical stimulation of muscle. In order to achieve this end, we propose to: 1) determine the appropriate muscles to be stimulated and the appropriate stimulation time period by measuring over a 24-hour period the imbalance in EMG activity of muscles which are believed to be involved in spinal curvature; 2) evaluate the long-term effects of electrical stimulation on the force production capabilities of muscle subjected to conditions which would be encountered in the patient; and finally, 3) implement a stimulation system in a pilot study involving approximately five patients using knowledge gained from the above.

Fitness Improvements and Physiological Responses to FES Exercise

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Purpose — The physical fitness of individuals with lower limb paralysis tends to deteriorate because of insufficient or inappropriate exercise. Upper body exercise training has been the primary means to enhance fitness. However, the paralyzed lower limbs tend to waste away because of disuse muscle atrophy and bone demineralization. Functional electrical stimulation (FES) of paralyzed leg muscles can provide a means to improve the integrity of the lower limbs. Therefore, it seems feasible that training regimes which include both voluntary arm exercise and FES leg exercise (performed separately and simultaneously) could enable higher levels of physical fitness to be attained by paralyzed patients.

The goals of the present research project are: 1) to evaluate the effectiveness of exercise protocols incorporating FES of paralyzed muscles for their potential in improving muscle strength and endurance, and general physiologic fitness; and 2) to evaluate the effectiveness of exercise protocols that incorporate simultaneous combinations of FES induced leg exercise and voluntary arm exercise for improving aerobic (cardiopulmonary) fitness.

Progress — FES exercise of paralyzed leg muscles is accomplished by using closed-loop electrical stimulator systems that incorporate either digital or analog circuitry. To date, knee extension exercise via stimulation of the quadriceps muscle groups with surface electrodes has provided the best results. Voluntary arm exercise is accomplished on a combination arm crank-wheelchair ergometer which had been previously designed and constructed.

Several studies have been performed using these exercise systems. The first was related to the development of standardized FES exercise protocols to provide safe and effective means of evaluating performance and to enhance the capacity of the paralyzed muscles for this form of exercise. We found marked improvements in muscle strength and endurance using a progressive intensity protocol where the load weights were gradually increased over a several week period. No known damage to the muscles, bones, or skin had occurred.

Preliminary Results — In evaluating physiologic responses to progressive intensity FES knee extension exercise, there were linear increases in oxygen uptake (VO_2) and pulmonary ventilation (VE). However, heart rate (HR) did not increase above the rest value. The maximal VO_2 achieved (20 pounds load) was less than two times the rest value. These relatively low maximal VO_2 and VE values and the lack of HR response cast doubt as to the ability of this exercise mode to provide much of a cardiopulmonary training effect.

It seems possible that the inability to perform FES exercise at higher levels is in part due to inadequate cardiovascular system adjustments. Insufficient blood flow to and from the exercising muscles would lead to the early onset of fatigue. Required adjustments (e.g., increased cardiac output and redistribution of blood from inactive tissues to the active skeletal muscles) are normally mediated through autonomic sympathetic stimulation. However, FES exercise is peripherally induced (which in effect bypasses the central nervous system), and many patients with impaired neuromuscular function (e.g., spinal cord injured) also have impaired autonomic function.

Another concern is the low efficiency that we found for spinal cord injured subjects performing FES knee extension exercise in comparison to able-bodied individuals performing the same task voluntarily. Indeed, the VO_2 during FES of the paralyzed muscles at 20 pounds load was similar to that for the voluntary exercise at 40 pounds load. This inefficiency may be due to histochemical characteristics of the paralyzed muscles, inappropriate stimulation patterns, and stimulation of inappropriate muscle fibers.

The most recent study incorporated spinal cord injured subjects performing maximal effort voluntary arm crank ergometry (ACE) and FES knee extension exercise separately and simultaneously. We found additive VO_2 and VE responses during the hybrid FES-ACE exercise, whereas the marked increase in HR was completely an effect of the voluntary ACE exercise. Knee extension performance as indicated by resistance to fatigue was significantly better during hybrid FES-ACE exercise than during FES alone. This may be due to enhanced sympathetic stimulation induced by the voluntary ACE exercise. These findings suggest that hybrid FES-ACE exercise may be used to increase active muscle mass and the maximal VO_2 achieved. This may improve the training capability of paralyzed individuals.

Future Plans — Future studies will include further development of FES exercise and hybrid FES-ACE exercise protocols to improve muscular and cardiopulmonary fitness. In addition, physiologic evaluations will be aimed at providing a better understanding of the limiting factors for FES exercise. Therefore, studies involving the determinations of central hemodynamic responses (e.g., stroke volume and cardiac output) and peripheral blood flow to the exercising muscles are being planned.

Electrical Stimulation of Paralyzed Muscle After Spinal Injury

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Purpose — Individuals with spinal cord injury have absent or diminished control over muscles that are innervated below the level of their injury. Many of these paralyzed muscles can be activated by electrical stimulation of the nerves leading to these muscles.

Progress — This study attempts to identify the therapeutic benefits of a regular program of electrically-induced leg reconditioning and exercise in a general population of veterans whose legs have been paralyzed by spinal cord injury. The study group consists of individuals with paraplegia and quadriplegia who are patients of the Spinal Cord Injury Service of the Veterans Administration Hospital at Hines, IL. This predominantly male population provides a diverse mix in terms of level and completeness of injury; actual age and years post-injury; height and weight; and the extent of cardiovascular, renal, urinary, skeletal, neuromuscular, peripheral vascular, cutaneous, and psychological complications brought on as a result of spinal injury. We did not consider individuals with damage to their spinal cord below T11, with severe peripheral vascular or cardiovascular problems, or with pressure sores in areas affected by stimulation for this protocol. To date, we

have completed baseline evaluations on 21 qualifying individuals. We screen an average of three or four additional potential candidates each month. For the most part, the qualifying individuals had incomplete quadriplegia (n = 10) or complete paraplegia at T11 or above (n = 7).

For this study we first measured torque and fatigue characteristics produced by an 100 ma stimulus (a 20 Hz train of 0.5 msec compensated monophasic pulses) delivered to the knee extensors via large (2 × 4cm) water soaked surface electrodes in alternating fashion (2.5 sec ON, 2.5 sec OFF). We then placed 18 of the individuals in a twice-daily, 6-day-a-week, 20-minute exercise protocol, with weekly assessments of progress. After four to eight weeks of electrically-induced exercise, some participants exhibited large increases in muscle force and fatigue-resistance while others showed little change. We are now attempting to correlate the extent of increases seen (if any) with our other observations.

Skeletal Muscle Adaptation to Electrical Stimulation: Rehabilitation of Fast and Slow Skeletal Muscle

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Purpose — We hypothesize that the functional electrical stimulaton (FES) protocol necessary for optimal muscle strengthening depends on the fiber type distribution within the muscle. Specifically, stimulation parameters used (frequency and duty cycle) may differentially affect fast and slow muscle fibers. Thus, it may be necessary to tailor a stimulation protocol to the fiber type distribution within the muscle.

Progress — Specific questions to be answered by this study are:

1) Does FES of skeletal muscle during immobilization prevent the atrophy observed with immobilization alone?

2) Does high frequency stimulation strengthen immobilized muscle to a greater extent than low frequency stimulation?

3) Do fast muscle fibers respond differently to high versus low frequency stimulation (same question for slow fibers)?

4) Does FES strengthen atrophied muscle to the same extent as normal ambulation?

5) Does FES strengthen a previously atrophied muscle to the same extent as it does a muscle undergoing atrophy, i.e., is it necessary to apply FES during the atrophic process or can it be applied later with the same results?

In order to address these questions, an animal model has been developed. Tibialis anterior and soleus muscles of New Zealand white rabbits are cast-immobilized and then activated for one hour/day × five days/week × four weeks. Following the stimulation treatment, contractile and morphometric properties of the muscle are measured.

Preliminary Results — Preliminary studies indicate that immobilized ankle position and stimulation frequency both significantly affect muscle strength and type S (slow) muscle fiber size. Further studies are underway to determine optimal stimulation protocol as well as FES efficacy in treating disuse atrophy.

Functional Electrical Stimulation for the Prevention of Pressure Sores

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Purpose — A new methodology for preventing pressure sores is under investigation that employs functional electrical stimulation (FES). A number of mechanisms have been identified through which FES can help prevent pressure sores. These include both immediate/dynamic and chronic effects of muscle stimulation. The immediate/dynamic effects include tissue undulation and increased blood flow. Chronic effects include increased strength and bulk of atrophied muscle, increased vascularization, and alteration of other tissue parameters.

Progress — Initial studies have focused on immediate/dynamic effects. Appreciable changes in seating interface pressures (greater than 20mm hg.) have been produced in able-bodied subjects using low stimulation levels (less than 50 percent of maximum). Ultrasonic imaging has verified that significant alteration of buttock shape and configuration are associated with these pressure alterations. Continuing research plans call for radioactive tracer studies to quantify stimulation effects on blood flow and clinical trials to evaluate both immediate and chronic effects of muscle stimulation.

Skeletal Muscle Adaptation to Electrical Stimulation: Specific Tension of Isolated Fast and Slow Muscle Fibers

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Sponsor: VA Rehabilitation Research and Development Service

Purpose — Long-term chronic stimulation of skeletal muscle causes conversion of fast muscle to slow muscle. This conversion takes place at the level of the single muscle fiber. It is therefore probable that much skeletal muscle which is stimulated therapeutically undergoes a fast-to-slow fiber type conversion. While slow muscle fibers can generate force for a longer period of time than fast fibers, the intrinsic strength of the two muscle fiber types is not known. Data obtained indirectly from studies of single motor units suggest that type S (slow) motor units generate less force per unit area than type FF or type FR (fast) motor units. Thus, fast-to-slow fiber type transformation secondary to FES may actually weaken muscle.

The purpose of this project is to directly measure the specific tension (i.e., intrinsic strength) of isolated fast and slow muscle fibers. Fibers are dissected from the tibialis anterior muscle of the leopard frog (*Rana pipiens*). Contractile and structural properties are monitored using the technique of laser diffraction.

Progress — Preliminary studies have demonstrated that the sarcomere behavior along the length of fast muscle fibers is very complex. Specifically, for a given muscle fiber undergoing a fixed-end contraction, fiber force developed may vary by as much as 50 percent depending on the relative movement of the different populations of sarcomeres along the fiber length. Generally, end-region sarcomeres shorten while center-region sarcomeres lengthen during the fixed-end contraction. In the slow muscle fibers, this type of divergent behavior does not occur.